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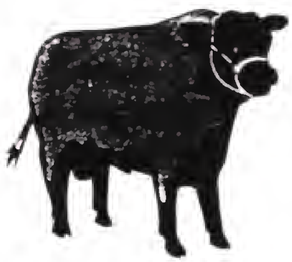
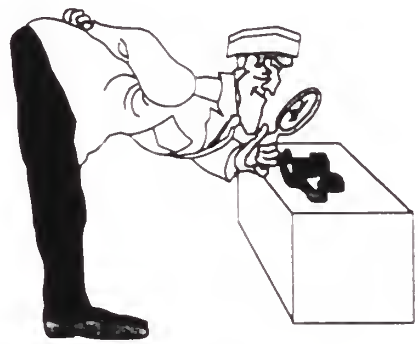
Subcommittee Report for the Pathogen Reduction Task Force

Identifying Research and Educational Needs





August 1994

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EXECUTIVE SUMMARY

INTRODUCTION

The USDA Pathogen Reduction Task Force (PRTF) was commissioned by Secretary Mike Espy in late 1993 to provide leadership, coordination and oversight of the Department's programs to ensure a safe and wholesome meat and poultry food supply. The task force, chaired by Acting Assistant Secretary for Marketing and Inspection Services, Patricia Jensen, has the responsibility for coordinating all Departmental activities associated with pathogen reduction for meat and poultry. Membership on the task force includes the Administrators of nine USDA agencies involved in various facets of research, regulation, and education on food safety and pathogen reduction. In addition, the task force has representatives from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

OBJECTIVES

The first task undertaken by the PRTF was achieving consensus regarding the following:

1. The "farm-to-table" concept serves as the strategic framework and underscores the importance of Departmental coordination along the entire continuum of pathogen reduction activities;

2. The Department must define research priorities in order to make knowledgeable decisions regarding strategic planning, Departmental coordination, and appropriate use of resources along this continuum;

3. The definition of research includes various disciplines and scientific methodologies, such as theoretical and experimental science and engineering, social and behavioral sciences, surveys, field studies, experimental pilot projects, technical and risk analyses, and modeling;

4. Potential overlaps and gaps of agency activities must be identified and recommendations made for enhanced interagency and intra-agency coordination and collaboration; and

5. A framework for a Departmental Food Safety Strategic Plan should build upon the PRTF's efforts.

PROCESS

Three technical subcommittees were established to focus on pathogen reduction research activities across the farm-to-table continuum. The subcommittees are: Live Animal, Slaughter and Processing, and Food Preparation and Consumption. Each subcommittee was asked to identify and prioritize the research areas and researchable questions thereunder. Opportunities for interagency collaboration and coordination within various segments of the continuum were defined.

The Live Animal ("Pre-harvest") area consists of activities dealing with on-farm management and husbandry practices, transportation of live animals, and marketing of animals prior to delivery at the slaughter establishment. The Slaughter and Processing area consists of in-plant slaughter activities, in-plant processing activities, and distribution and transportation of raw and finished products. The Food Preparation and Consumption area consists of retail food operations (sales, marketing, food service, institutional feeding, and catering) and consumer preparation and handling.

As each subcommittee began its work, certain assumptions were provided to guide those deliberations. First, the subcommittees were to focus on microbial issues affecting food safety and pathogen reduction. Second, the microorganisms of interest were those identified in Healthy People 2000 (*Salmonella* species, *Salmonella enteritidis*, *Campylobacter jejuni*, *Escherichia coli* O157:H7, and *Listeria monocytogenes*) and those microorganisms further identified by CDC as significant in foodborne illness of meat and poultry (*Staphylococcus aureus* and *Clostridium perfringens*). Third, the subcommittees were asked to identify the timeframes within which particular aspects of the researchable questions could be delivered. The subcommittees identified immediate (within one year), short term (within two years), or long term (more than two years) research time lines. Fourth, the subcommittees were to examine how the research areas might be prioritized within each segment and also how the research areas might be prioritized across the entire continuum.

RESEARCH AREAS

The common research areas identified across subcommittees are:

- Epidemiology
- Microbial Physiology/Ecology
- Hazard Analysis and Critical Control Point (HACCP)
- Economic Analysis/Risk Assessment
- Risk Communication
- Technology Development and Transfer
- Education

These provided the framework upon which each subcommittee deliberated and reached consensus on researchable questions. A common thread which ran through their analyses is the need for a comprehensive research infrastructure and effective educational delivery systems. These will enhance the capacity of USDA to ensure the production, processing, and consumption of safe meat and poultry products.

RECOMMENDATIONS

1. Research Areas and Researchable Questions. **The research areas and researchable questions formulated and identified by the subcommittees should be accepted by the USDA Pathogen Reduction Task Force as the initial focus for defining current research needs within USDA.** The research areas and researchable questions should be made available to the scientific community at large and to the general public as a stimulus for public and private sector research and development that supports USDA's food safety and pathogen reduction research needs. **The subcommittees also recommend that the Department further consider and test the effectiveness of alternative methodologies and tools that can be used to establish research priorities.** Additional refinement of the subcommittees' initial efforts in prioritizing and ranking research areas and researchable questions is needed. These subsequent efforts could supplement further development of an effective, comprehensive strategic plan.

2. Strategic Planning. **The effectiveness of USDA's pathogen reduction efforts will be enhanced by development of a strategic plan which defines specific goals and coordinates USDA's scientific, managerial, and policy resources.** This report cites four critical needs essential to this effectiveness: interagency research coordination, the adaptation of HACCP concepts throughout the continuum, risk analysis, and public health and production animal surveillance and monitoring. A means for assuring these needs are met is to develop a strategic plan built upon the work and recommendations presented here. A working group on strategic direction and planning should be established to integrate USDA's pathogen reduction efforts into specific goals.

3. Interagency Coordination. **Formal interactions at both the policy and research scientist levels should be established.** At the policy level, a group, such as the Pathogen Reduction Task Force, should meet annually to develop advisory recommendations on broad research areas which need to be addressed in the subsequent 24-48 months. These advisory recommendations for USDA research should be disseminated widely to both the USDA research community and the public and private sector scientific community at large. The advisory recommendations stemming from the policy level deliberations can subsequently be used to foster increased interaction and planning among USDA scientists through existing interagency collaborative groups, such as the FSIS/ARS/APHIS Research Planning Workshop and the Interagency Work Group on Preharvest Activities.

4. Risk Analysis. Each subcommittee made recommendations for research in risk analysis, differing only in specific techniques and applications. These recommendations are that USDA should:

(a) **Continue and strengthen its research on the development of applicable techniques, concepts, and data that will allow accurate estimates of the impact of changes in food production, preparation, or regulation**; and

(b) **Continue to encourage CDC to conduct research, surveillance and its subsequent analyses that will better characterize risks for foodborne pathogens.**

(c) **Undertake research on food safety risk communication to accurately determine current food safety knowledge and practice, capabilities of educational delivery and public information systems, and based on these research findings implement needed improvements in risk communication programs.**

5. HACCP. **Research into the identification of hazards, critical control points, critical limits, and techniques for monitoring and verification of HACCP systems is necessary.** This research has been critical to the development of USDA's plan for implementation of mandatory HACCP systems in Federally inspected meat and poultry plants and this research will be critical for the voluntary application of HACCP concepts elsewhere in the continuum. An integral part of USDA's HACCP research is the assessment of new intervention strategies and technologies to broaden the range of options available to managers to reduce and control pathogens. The implementation of HACCP will also call for extensive education and training at all levels of government, food production, manufacturing, retail food preparation, and consumption.

6. Public Health and Production Animal Surveillance and Monitoring. **Timely public health surveillance information is critical for the identification of both new foodborne threats to public health and the re-emergence of known foodborne pathogens.** An integral part of any system for controlling foodborne disease is the acquisition of pertinent public health data. As a principal user of public health surveillance information, USDA should periodically provide Health and Human Services (HHS) with a clear definition of our needs in this area. Additionally, USDA should build upon the public health liaison capacity presently established with CDC and enhance sharing of public health and animal production monitoring and surveillance data for human pathogens.

DESCRIPTION OF CURRENT EFFORT

Under the mandate of the Secretary of Agriculture, the Acting Assistant Secretary for Marketing and Inspection Services chairs the USDA Pathogen Reduction Task Force (PRTF). Members of the PRTF include Administrators of the Agricultural Marketing Service, the Animal and Plant Health Inspection Service, the Agricultural Research Service, the Cooperative State Research Service, the Extension Service, the Economic Research Service, the Food and Nutrition Service, the Food Safety and Inspection Service, and the Packers and Stockyards Administration. In addition, the PRTF has representatives from the Food and Drug Administration and the Centers for Disease Control and Prevention.

The mission of the PRTF is to coordinate all Departmental activities associated with pathogen reduction in meat and poultry, one of the largest and most complex public health initiatives ever attempted. As part of the planning and coordination activities, the PRTF sought to identify the highest priority research and consumer education/information topics for reducing pathogens in meat and poultry. USDA also conducts a variety of pathogen reduction activities in other commodities, such as eggs, egg products, and dairy products. Research activities in these other commodities are beyond the scope of this particular effort. The recommendations contained in this report focus only on meat and poultry.

To facilitate the work of the PRTF, a subdivision of Departmental activities across the farm-to-table continuum was found useful. Three subcommittees, formed around specific portions of the farm-to-table continuum, were organized: Live Animal, Slaughter and Processing, and Food Preparation and Consumption. Based on their agency's responsibilities and interests, each of the administrators identified highly qualified individuals to serve on these subcommittees.

The Live Animal area consists of activities dealing with on-farm management and husbandry practices, transportation of live animals, and marketing prior to the delivery of animals at the slaughter establishment. Slaughter and Processing consists of in-plant slaughter activities, in-plant processing activities and distribution and transportation of raw and finished products. The Food Preparation and Consumption area consists of retail food operations (sales, marketing, food service, institutional feeding establishments, catering, etc.) and consumer activities.

The objectives of the subcommittees were to identify researchable questions in the food chain continuum and promote interagency coordination where there is a lack of pertinent information regarding pathogen reduction and prioritize research initiatives that address the information deficiencies. The subcommittees began this process by defining broad research areas. Next, researchable questions were formulated to support appropriate interventions and to identify immediate (less than one year), short term (within two years), and long term (more than two

years) initiatives. Interagency coordination and project/program initiatives necessary to achieve such interventions were identified as were other gaps in either knowledge or authority necessary to support effective intervention. A final objective was to achieve preliminary prioritization or ranking of research areas, both within each segment of the continuum and across the entire continuum. The former was accomplished by obtaining a consensus within each subcommittee and the latter was accomplished by use of a decision matrix.

CURRENT RESEARCH ACTIVITIES

The Department of Agriculture has had a longstanding involvement in research on the safety of agricultural commodities. Included in this effort is a strong commitment to provide research on the microbiological safety of meat and poultry that is needed to have a science-based inspection system. The Department's research activities and related programs span the farm-to-table continuum, encompassing the three broad areas being considered by the PRTF subcommittees. The following section provides an overview of some of the Department's recent accomplishments and current research activities. This includes descriptions of some interagency research collaboration efforts involving commodities other than meat and poultry, as a way of demonstrating the scope of present USDA research activities. A detailed account of research activities and accomplishments in foodborne pathogen characterization and control that has been conducted or funded by USDA agencies is well beyond the scope of the current report. In addition to the selected examples provided below, further examples categorized by agencies are presented in Appendix A.

Live Animal Research

The integrated system of operations associated with the production, slaughter, manufacture, distribution, sale, and preparation of meat and poultry products is highly complex. Potentially, foodborne pathogens can enter at any of the myriad of individual steps. However, for a number of pathogens (e.g., *Salmonella*, *Campylobacter*, *E. coli* O157:H7), the initial site of contamination appears to be during animal production. Unfortunately, it is currently not possible, in most instances, to identify animals that internally harbor human pathogens. Further, it is not presently known how the microorganisms maintain themselves within the animal, or even the sources of the pathogens in the farm environment. Without this knowledge it is not possible to design live animal production programs to help ensure that animals are free from bacteria of public health significance. USDA agencies are currently involved in live animal research efforts to address these underlying issues. These agencies are the Animal and Plant Health Inspection Service (APHIS), the Agricultural Research Service (ARS), Cooperative State Research Service (CSRS), the Food Safety Inspection Service (FSIS), the Economic Research Service (ERS), and the Packers and Stockyards Administration (PSA). Approximately two thirds of the current live animal research is focused on production animals, with the remaining third targeted to research on *Salmonella enteritidis* prevention in eggs and poultry.

Current live animal research activities can be subdivided into several broad areas, which include:

- basic microbiological studies on the genetics, physiology, pathogenicity, and virulence of foodborne pathogens, particularly in relation to its ability to colonize and maintain themselves in the host animal,
- identification of factors that influence the sources and spread of pathogens in the farm environment and the prevalence and extent of pathogens in production animals,
- development of interventions for preventing, controlling, or eliminating pathogens in production animals,
- evaluation of the influence of farm management practices on the incidence of pathogens,
- development of improved diagnostics, and
- development of improved traceback systems.

Some specific examples of the research either planned, underway or completed in the live animal area include:

- Surveys of dairy and beef cattle to determine sources and incidence of *E. coli* O157:H7 and other pathogens, and identify the significance of risk factors such as meat composition, regional differences, imports, consumption patterns, grazing on slurry fields, and feeding ionophores (APHIS).

- Development and evaluation of rapid serological and molecular biological diagnostic tests to identify live animals that harbor *E. coli* O157:H7, *Salmonella*, *Campylobacter*, and *L. monocytogenes*, etc. (APHIS, FSIS, ARS, CSRS).

- Determination of the effects of stress, feed withdrawal, and other related factors on the level of pathogens in animals during rearing and transport (APHIS, ARS, FSIS).

- Surveys of the extent of *Salmonella enteritidis* contamination in egg-laying flocks (APHIS).

- Development and assessment of the potential use of probiotics, competitive exclusion, and vaccines to prevent *Salmonella* (including *S. enteritidis*) and *Campylobacter* in poultry and *E. coli* O157:H7 in cattle (APHIS, ARS, CSRS).

- Development and evaluation of techniques such as phage typing, plasmid profiles and fingerprinting as epidemiological tools for determining sources and transmission patterns of *Salmonella enteritidis* in poultry flocks (APHIS).

- Identification of interventions and management practices that can be used to control colonization of *Salmonella* and *Campylobacter* infections in eggs and chicks in hatcheries and during subsequent rearing (ARS, APHIS).

- Determination of the factors associated with virulence of *Salmonella enteritidis* in chickens as the basis for development of improved diagnostics and new approaches for prevention or control of infections (ARS).

- Assessment of on-farm costs to control *Salmonella enteritidis* in egg-laying flocks (ERS).

- Development of a broiler on-farm HACCP demonstration project as means to enhance *Salmonella* control (ES).

- Elucidation of molecular biological factors associated with colibacillosis in swine and cattle (ARS).

- Determination of the adequacy of services, and evaluating facilities & handling procedures in promoting reasonable animal care (PSA).

- Evaluation of the accuracy of commercial and conventional methods to identify mastitis pathogens and the effect of hygienic and therapeutic practices on the distribution of these microorganisms (CSRS).

Slaughter and Processing Research

Traditionally, meat and poultry slaughter and processing operations have been a focus area for much of the research effort associated with control of pathogenic microorganisms in products of animal origin. In part, this reflects the past emphasis on slaughter and processing as a likely site to implement intervention strategies, and the long standing activities and interactions between the Department's research (ARS, CSRS, ERS) and regulatory (FSIS) agencies. In addition to meat and poultry processing, the Department (primarily the Agricultural Marketing Service, AMS and ARS) also has research of a more limited scope on the processing of egg products. There has been relatively little research directly related to the distribution of meat and poultry after manufacture. However, much of the research generated for slaughter/processing operations is also pertinent to retail and home food preparation, and the boundaries between these two subcommittee areas are often indistinct.

Current slaughter/processing research activities can be subdivided into several broad research areas that include:

- evaluation of the prevalence and extent of pathogens in meat and poultry products,
- development and evaluation of methods for the detection and enumeration of pathogens and indictor organisms,
- basic microbiological studies on the genetics, physiology, pathogenicity, and virulence of foodborne pathogens,
- assessment of current intervention strategies and the development of new or novel interventions,
- development of risk assessment and predictive microbiology methods,
- assessment of new food technologies and food ingredients,
- evaluation of the economic impact of foodborne disease.

Complementing the research effort, there has been a relatively small number of educational programs targeted to translate the knowledge gained through research and to develop formats which are more useful to the various segments of the meat and poultry industries and their associated regulatory agencies.

Selected examples of various aspects of slaughter/processing research are provided below.

- Baseline studies on pathogens in steers/heifers, cows/bulls, broiler chickens, market hogs, turkeys, disabled/"downer" cows, and ground beef (FSIS, AMS).

- Use of bacteriocin and bacteriocin-producing bacteria to control pathogenic bacteria such as *L. monocytogenes*, *Salmonella*, and *Clostridium botulinum* (CSRS, ARS).

- Development and assessment of bacteriocidal washes such as organic acids, trisodium phosphate, oxidative alkali treatments, lactoperoxidase, etc. for the inactivation of pathogens during slaughter (CSRS, ARS, FSIS).

- Development or assessment of serological, gene probe, and PCR assays for *E. coli* O157:H7, *L. monocytogenes*, *C. perfringens*, *Campylobacter*, and *Salmonella* (ARS, FSIS, CSRS).

- Development of indicator tests for assessing the integrity of slaughter, processing, and distribution operations for meat and poultry products (ARS, CSRS).

- Improvement of current enrichment and pre-enrichment techniques, and the development of alternate methods that eliminate or reduce the need for enrichment, enhance detection of injured cells, or provide a means for acquiring "real-time" measures of pathogen levels (eg. biosensors) (FSIS, ARS, CSRS).

- Development, assessment, and adaptation of rapid diagnostic tests that can be used in-plant (FSIS, AMS, ARS, CSRS).

- Evaluation of new technologies such as the effect of modified atmosphere packaging on the growth of foodborne pathogens, including *C. perfringens*, *L. monocytogenes*, and *C. botulinum*, the microbiological impact of poultry scalder redesign, and the microbiological impact of water reuse (ARS, CSRS, FSIS).

- Development of mathematical models for predicting the growth, non-thermal inactivation, or thermal resistance of *L. monocytogenes*, *Salmonella*, *E. coli* O157:H7, *C. botulinum*, *S. aureus*, *Yersinia enterocolitica*, *Bacillus cereus*, and *Aeromonas hydrophila* that can be used to enhance microbial risk assessments capabilities (ARS).

- Assessments of the cost of foodborne disease and food safety regulations (ERS, CSRS).

- Development of new interventions such as irradiation, surface pasteurization, ohmic heating, seroselective adsorption, UV and intense white light, biocontrol, and dehairing prior to evisceration (ARS, CSRS, FSIS, AMS).

- Identification and characterization of virulence related factors such as pyschrotrophic growth in *L. monocytogenes*, *Bacillus cereus*, and *Salmonella*, sorbitol metabolism in *E. coli* O157:H7, attachment of *Salmonella* and *L. monocytogenes* to epithelial tissue (ARS, CSRS, AMS).

- Identification of the mechanisms by which *Salmonella*, *E. coli* O157:H7, and other enteric bacteria attach to meat and poultry tissue (ARS)

- Identification and validation of HACCP models for small locker and meat processing plants dealing with raw product (ES)

Food Preparation and Consumption Research

Of the three broad areas considered by the PRTF subcommittees, food preparation and consumption has the smallest amount of resources devoted to laboratory-based research. Alternately, this area has the largest involvement in sociological, economic, and educational research and related activities.

Current microbiological research in this area is conducted or funded by ARS and CSRS, respectively. As previously mentioned, some of the research needs related to this area are addressed under slaughter/processing research. The limited involvement of USDA in laboratory-based research related to retail food preparation reflects the Department's traditional regulatory focus, with FSIS inspecting meat and poultry manufacture and FDA overseeing retail food operations. This appears to be an area where alternate sources of research information need to be identified (e.g., FDA). The Department's research requirements that are not covered by these alternate research organizations need to be identified and considered for future research priority setting. Examples of current microbiological research include:

- Assessment of the "cleanability" of plastic and wood cutting boards (ARS).
- Thermal inactivation requirements for *E. coli* O157:H7 in food service operations (CSRS)
- Effect of transitory temperature abuse on the growth of *E. coli* O157:H7, *L. monocytogenes*, and *Shigella flexneri* (ARS).
- Identification of microbiological indicators of temperature abuse (ARS).

The economic research related to food preparation and consumption is conducted by ERS, while research and associated activities applicable to food preparer education and consumer attitudes is being conducted by CSRS, ERS, ES, and FSIS. Some examples of activities in this area include:

- Determination of consumer attitudes related to foodborne disease, willingness to pay for enhanced safety, and balancing of relative risks (ERS, CSRS).
- Estimation of the costs of foodborne illness (ERS)
- Estimation of the costs estimates associated with Guillain-Barre Syndrome caused by *Campylobacter* (ERS).

- Development of model food preparer education programs (ES).
- Development of education programs for at-risk consumers, pregnant women and mothers, and children (FSIS, FNS)
- Development of education packets for safe food handling and HACCP (FSIS).

SPECIFIC SUBCOMMITTEE RECOMMENDATIONS

The main work of the subcommittees was the identification of research areas and researchable questions, the relative ranking of research areas within discrete segments of the farm-to-table continuum, and the identification of timeframes within which specific researchable questions are anticipated to be answered. This summary attempts to provide a glimpse into the scope of the discussions that surrounded the identification and formulation of the research areas and related researchable questions. **The primary recommendation from the subcommittees is that the USDA Pathogen Reduction Task Force accept the specific recommendations on research and researchable questions that evolved from the subcommittees' deliberations.**

The identification of particular research areas and questions should not be taken as an indication that USDA scientists and policy-makers have not addressed these areas nor should it be viewed as an indication of a gap in USDA's knowledge. Rather the questions stem from taking a knowledge based approach to the task. Each question builds on a foundation of knowledge, partially or fully explored, that is a necessary antecedent for subsequent research initiatives. The questions define knowledge known or needed by USDA scientists to proceed with development of policy alternatives. Subcommittee deliberations touched repeatedly on issues related to policy but such discussions were outside the scope of the subcommittees' charge.

The subcommittees also considered different approaches and criteria for establishing a priority ranking among research areas. Several approaches and criteria for the priority-setting were explored but time constraints did not permit more than an initial assessment of the potential approaches and criteria. A more rigorous evaluation and validation of alternative methodologies for research priority setting is needed. **The subcommittees thus recommend that the Department further consider and test the effectiveness of alternate methodologies that can be used to establish research priorities.** A fuller presentation of the subcommittees' discussions on the relative ranking of research areas can be found in Appendix E.

This next section provides a summary of the research areas and researchable questions defined within each of these areas as set forth by the separate subcommittees. Appendices B (Live Animal), C (Slaughter/Processing) and D (Food Preparation and Consumption) contain detailed narratives and timeframes identified for each of the researchable questions.

Live Animal Subcommittee

A. Ecology and Epidemiology

1. What improvements in diagnostic techniques are required for effective detection of known and emerging human pathogens in live animals?

2. What is the ecology of the pathogen in the production environment?

3. What is the role of the asymptomatic carrier in the transmission of human disease?

4. What epidemiological data are required to identify sources of human disease associated with animal production and to identify factors that contribute to the prevalence and distribution of that pathogen?

B. Pathogenicity/Virulence/Microbial Physiology/Genetics

1. How does the human pathogen colonize and maintain itself in a production animal?

2. What information or techniques are required to support development of improved diagnostic tests that can distinguish strains that are pathogenic and non-pathogenic to humans?

3. What information is needed about animal and microorganism interactions to develop new strategies for preventing or eliminating colonization by the organism?

C. Live Animal Production (Pre-harvest) HACCP

1. What information is needed for an understanding of the impact of good production practices on the potential for production animals to serve as a source of human foodborne disease?

2. What improved or alternate intervention strategies are required that can be used to prevent or control human pathogens in production animals?

3. What techniques need to be developed to implement, monitor, and validate live animal (pre-harvest) HACCP programs?

D. Economic Analysis/Risk Assessment

1. What is the cost/benefit of HACCP interventions?

2. What statistical and epidemiological techniques are required in order to be able to extrapolate the detection of a pathogen on a limited number of farms to a realistic estimate of disease transmission/exposure on a national basis?

3. How can existing risk assessment models for animal disease be expanded to include human pathogens?

E. Risk Communication/Technology Transfer

1. What is the information needed, both to and from, the different target populations (consumers, producers, regulatory agencies, Congress)?

2. How do you get the information to the target populations in the most efficient manner?

F. Traceback

1. What existing technologies can be expanded or consolidated to improve traceback capabilities?

2. What alternate technologies, such as "genetic fingerprinting", could be developed to identify unequivocally the identity of an animal and the products derived from it?

3. How can current technologies be modified to overcome concerns related to the introduction of non-food components in a food system?

Slaughter and Processing Subcommittee

G. Prevalence/Incidence/Sources

1. What methods for sampling and detection of microorganisms exist? How can they be improved or replaced with new techniques?

2. What are the levels and sources of pathogenic microorganisms in meat and poultry products at various stages along the food chain continuum?

3. How do we evaluate and assess the likely impact on how prevalence, level, and sources are altered by changing procedures?

H. Microbial Physiology/Ecology

1. What effects do various physical and chemical parameters have on bacterial survival and growth?

2. What are the mechanisms of bacterial attachment/detachment to tissues? To processing equipment?

3. What knowledge of microbial physiology and genetics is needed to provide a basis for new developments for the detection and control of pathogenic microorganisms?

I. Slaughter/Processing HACCP

1. What is the scientific basis for identifying hazards associated with meat and poultry products and establishing CCPs and critical limits?

2. What methods for monitoring critical control points or verifying HACCP operations are effective in relation to sensitivity/accuracy, cost, timeliness, ease-of-use, etc.?

J. Technology Development and Transfer

1. What current technologies exist or need to be developed to control or reduce pathogens? How can these technologies be adapted to food operations?

K. Economic Analysis and Risk Assessment

1. What currently available mathematical models exist for predicting the growth, inactivation, and survival of foodborne pathogens? How can these models effectively predict the microorganisms' behavior during slaughter, processing, storage and distribution? Have the models been appropriately validated?

2. What assessment techniques could be developed to evaluate the likely impact and risk associated with changes in slaughter and processing?

3. What is the cost/benefit of education versus regulation (compliance)?

L. <u>Risk Communication and Education</u>

1. What resources and techniques need to be available to train industry, Federal, state, and local regulators in the concepts and practices of HACCP?

2. How can an expert system be developed that would assist the inspector in making regulatory decisions and help standardize inspectional activities?

3. What information is needed by different target populations (consumers, regulatory agents, processors, producers, etc.)?

4. How do you get the information to the target populations in the most efficient manner?

5. How do we efficiently and effectively communicate food safety risks to target populations?

Food Preparation and Consumption Subcommittee

M. <u>Prevalence/Incidence/Epidemiology</u>

1. What is the prevalence and incidence of human pathogens in meat and poultry and what is the relationship to foodborne illness?

2. What are the sources, points of entry, and opportunities for proliferation of bacteria within the retail and home portions of the food chain?

3. What are the methods for sampling and detection of microorganisms and associated surveillance systems?

N. <u>HACCP in Retail and Home Food Preparation</u>

1. What is the scientific basis for identifying hazards, establishing Critical Control Points (CCPs), and setting critical limits in the home/retail setting?

2. What methods for monitoring CCPs and verifying HACCP operations exist or can be developed? Can existing ones be improved?

O. Consumer and Food Preparer Education/Risk Communication

1. How can we effectively and responsibly communicate food safety risks?

2. What types of monitoring system and evaluation techniques are needed to assess knowledge levels of preferences of food preparers and consumers about food preparation and handling practices and interventions?

3. How can we identify which population segments are not receiving adequate food safety information and how can we evaluate/improve or develop alternate delivery systems to reach these populations?

P. Economic Analysis and Risk Assessment

1. What are the sizes and characteristics of population segments at increased risk for foodborne disease?

2. What assessment techniques could be developed to evaluate the likely economic impacts (including impacts on consumer demand) associated with changes in technologies and changes in food safety behaviors and practices of food preparers?

3. What assessment techniques could be developed to evaluate the risks associated with changes in technologies and behaviors as practiced by food preparers and consumers? How can we determine if unintended hazards are created, including changes in occurrence and severity of hazards?

4. What administrative and regulatory procedures or incentives need to be used to encourage the development and adoption of new technologies?

Q. Technology/Technology Transfer

1. What intervention or control technologies exist or need to be developed to decrease risk of foodborne pathogens in a retail/home food preparation setting?

2. What retail practices can be altered to optimize food safety?

3. What type of 'tools' are available or can be adapted or developed for use in the food service industry or in the home?

4. How can information technology be used/enhanced within USDA to better support research and other activities?

GENERAL RECOMMENDATIONS

While the deliberations of each subcommittee can be considered independently, there remains a significant degree of similarity in the issues framed by these deliberations. There were five major issues that served as foundational underpinnings or cross-cutting issues throughout the farm-to-table continuum. These five issues were: the need for strategic planning, the need for interagency coordination, the need for risk analysis, the application of HACCP concepts, and the need for medical intelligence on foodborne illnesses. Consideration of the recommendations contained within these five issues, along with the materials and recommendation presented in "SPECIFIC SUBCOMMITTEE RECOMMENDATIONS" section of this report, constitute the substance of the subcommittees' report to the USDA Pathogen Reduction Task Force.

Strategic Planning

The effectiveness of USDA's pathogen reduction efforts will be enhanced by conscious movement towards specific goals and by coordination of USDA's scientific, managerial, and policy resources. This report cites four critical needs essential to this effectiveness: interagency research coordination, the adaptation of HACCP concepts throughout the continuum, risk analysis, and public health and production animal surveillance and monitoring. The means by which these needs can be assured is through strategic planning.

Development of a strategic plan for USDA's pathogen reduction efforts was recognized during both task force and subcommittee meetings as the foundation for continued success in this endeavor. It is the recommendation of the subcommittees that such a strategic plan be developed, building on the work presented here. This would be the first tier of departmental strategic planning that could be undertaken.

There are two other levels of strategic planning that could also be constructed. The second level is a strategic plan for food safety research, regulation, and education on meat and poultry, of which the strategic plan on research in pathogen reduction is a element. This second level would broaden the strategic focus from microbial issues to include chemical and physical issues and the full range of biological issues (e.g., disease and pathology). Both APHIS and FSIS presently have technical analysis groups composed of well-respected scientists within government, the private sector, and academia working on development of reports that identify the hazards from farm-to-table, the known intervention and control mechanisms, the additional research requirements, and the potential innovations in regulation and control of physical, chemical, and microbial hazards. These reports are expected to be available within the next few

months. Together with the material presented in this report, the skeletal framework for this second tier of strategic planning appears to be present.

The third level is a strategic plan for food safety research, regulation, and education on all commodity products. This latter level of planning would incorporate planning for meat, poultry, eggs, dairy products, grains, vegetables. This third tier of strategic planning would be extremely comprehensive and would go beyond the scope of the presently identified mission of the USDA Pathogen Reduction Task Force. The subcommittees believe, however, that the task force endeavors could serve as a model for the necessary interagency collaboration that would be essential to building this level of a strategic plan. However, the subcommittees have assembled an extensive bibliography of reference sources that cover a variety of commodities. Over the past decade, extensive interagency efforts both internal and external to USDA have been undertaken to document food safety hazards, interventions, and controls. The subcommittees believe that development of such a comprehensive plan is achievable. The subcommittees thus recommend that USDA undertake the sequential development of these strategic plans.

Interagency Research Coordination

Critical to the effective use of the limited resources available for research on issues related to pathogen reduction is effective coordination and collaboration both among researchers and between the research agencies and the end-users of the information. Such coordination is not only critical to ensuring adequate identification of priority needs, but also important for establishing realistic research goals and timeframes, preventing unplanned redundancies of effort, improving the design and interpretation of research projects and protocols, and enhancing the transfer of the knowledge to the groups that must apply it to the control of foodborne pathogens in meat and poultry.

Current Status:

The Pathogen Reduction Task Force and its supporting subcommittees represent one of the Department's largest efforts, as measured by the number of agencies participating, in the coordination of research to address a food safety issue. However, it is by no means the only effort to enhance food safety research through coordination and collaboration. The Department's regulatory and research agencies have a long history of working together. Specific examples range from informal collaborations between scientists to formal Memoranda of Understanding between agencies. A noteworthy example in the latter case is the relationship between FSIS and ARS. The system by which the two agencies identify, prioritize, and report research that ARS undertakes in

support of FSIS' research needs is often cited by the scientific community as an example of effective research partnerships.

In keeping with its role as the Department's intramural research agency, ARS has traditionally had the greatest degree of research collaboration with other USDA agencies. There are formal processes for the identification and execution of research in support of FSIS, AMS, FGIS, and APHIS. The interaction between CSRS and other USDA agencies has also been extensive, though often more informal. The needs of other USDA agencies have often been identified through participation on CSRS regional research committees. Recently CSRS has become more involved in direct research coordination through funding of special grants such as the Food Safety Consortium. This group of three universities and CSRS has been increasingly involved with FSIS and ARS in their yearly research planning processes. There is an increasing number of examples of coordination and research support among USDA regulatory agencies, such as FSIS and APHIS investigation of *E. coli* O157:H7 sources, AMS' support of FSIS' evaluation of ground beef for *E. coli* O157:H7, collaboration between APHIS and AMS on control of *S. enteritidis* in eggs and egg products, and FSIS input into ERS' estimation of human illness costs of *E. coli* O157:H7.

In addition to intradepartmental coordination, USDA agencies have had extensive interactions with other Federal and state agencies involved in food safety research and related initiatives. In particular both regulatory and research agencies within USDA have coordinated their residue research and information sharing activities with FDA and EPA. For example, scientists from FSIS, ARS, FDA, and EPA meet yearly to evaluate drug residue methods development plans and objectives. Likewise, FDA, APHIS, AMS, FSIS, ES, and PSA established, through a memorandum of understanding (MOU), the Interagency Residue Control Group as a means of enhancing information sharing and problem solving. The Preharvest Pathogen Reduction Working Group was founded by FSIS in 1992 and was the primary interagency coordination effort in live animal production issues for APHIS, ES, PSA, FSIS, and FDA. Also in 1992, USDA and FDA signed a MOU to work together to reduce *Salmonella enteritidis* infections. Food irradiation is another example of intergovernmental coordination. ARS, FSIS, and ERS have had over a decade of ongoing involvement with FDA and the Department of Defense on the use of low dose irradiation for control of pathogens. More recently, ARS scientists have been interacting with the Department of Energy on both irradiation and the development of advanced detection methods.

Since food safety issues are often global in scope, scientists within USDA have increasingly attempted to coordinate and collaborate with scientists from other countries. For example, representatives from the Canadian Department of Agriculture are among

the participants at the annual FSIS/ARS research planning meeting. Another example is the discussions currently underway between ARS, FDA, and FSIS with their counterparts in the United Kingdom, Australia, and Canada to develop mechanisms for coordination of research in predictive food microbiology and its application to HACCP implementation and inspection activities. Historically, Office of International Cooperation and Development (OICD) has played a pivotal role developing ties and coordination between USDA scientists performing food safety research and their foreign counterparts. For example, pathogen reduction has been a major thrust of the U.S. - Irish Agricultural Research Exchange Program.

Recommendations:

Departmental efforts to identify and coordinate research needs in food safety and pathogen reduction are an excellent start and should be formalized to foster their further development. Two levels of interaction and cooperation are needed. The first is at the policy level. A committee such as USDA's Pathogen Reduction Task Force should meet annually to develop advisory recommendations on broad research areas that will need to be addressed in the subsequent 24 - 48 months to support the Department's initiatives and programs. These advisory recommendations on broad strategic direction for USDA research should be widely disseminated to insure a clear understanding by both USDA researchers and the scientific community at large of the Department's research needs and objectives.

The second half of the equation for increased coordination and collaboration is to foster and increase the interaction and planning among USDA scientists through existing interagency groups such as the FSIS/ARS/APHIS Planning Group and the Interagency Work Group on Preharvest Activities. For example, the annual FSIS/ARS/APHIS Research Planning Meeting can be expanded to include a wider range of participants. Minimally, there should be increased representation from agencies represented on the USDA Pathogen Reduction Task Force. Likewise, the recent trend toward inviting representatives from other governmental agencies, land grant colleges, industry and research groups, such as has been done in the Interagency Work Group on Preharvest Activities, should be encouraged. It is also recommended that an interagency panel be formed to identify additional means for enhancing interactions.

Risk Analysis

Risk analysis is a relatively new process. It developed into an organized discipline over the last twenty years largely in response to Federal laws for protection of public health and the

environment. The objectives of risk analysis are to help decision makers identify actual public health or environmental hazards associated with substances or activities, determine an appropriate risk abatement strategy, and effectively communicate that strategy to interested parties. Thus, the risk analysis process consists of three phases: risk assessment, risk management, and risk communication.

Risk analysis provides a group of potentially powerful tools that could assist USDA policy makers in reaching decisions pertaining to the safety of meat and poultry. USDA regulatory agencies have extensive experience in performing qualitative risk assessments. However, adoption of systems approaches for assuring the safety of foods (e.g., HACCP) and the increasing sophistication of food formulation and manufacturing technologies are two of a number of reasons why pathogen reduction efforts will require the development of quantitative risk assessment capabilities. Realizing the potential benefits of these methods, USDA regulatory agencies have been strong advocates for the involvement of USDA scientists in risk assessment research.

Risk management, the second component of risk analysis, is explicitly a policy activity that identifies and evaluates feasible regulatory and non-regulatory risk abatement options. While risk assessment is a fundamental ingredient of risk management, risk management must consider scientific evidence in the context of social, political, and economic concerns as well. It is important that risk assessment and risk management activities be distinct but interactive to preserve scientific objectivity in the assessment process. Risk assessments are intended to be technical and scientific and should not be considered policy alternatives or regulatory consequences. For that reason, risk assessment should never be used to recommend a solution or course of action.

Risk communication and education, the third component, may be the intrinsic key to the success of any food safety program. Even the most valid technical information will be of little use if it is not communicated to and understood by the target individuals. The researchable questions identified by the subcommittees focus on common concerns, such as, what information is needed by particular individuals, how that information is delivered to those individuals, and how USDA can responsibly communicate about risk to individuals.

Current status:

The advantages of being able to conduct quantitative risk assessments for meat and poultry products are clearly evident. Regretfully, the techniques for performing quantitative microbiological risk analysis are either in their infancy or are conceptually incomplete or non-existent. Further, research of this type is interdisciplinary and requires intergovernmental cooperation. Risk assessments require comprehensive risk characterization. Research directly investigating pathogen-host relations in human studies is generally are not conducted by USDA, but they are within the research mission of agencies such as CDC.

In the risk communication and education phase, the principal questions focus on identifying knowledge and information that must be communicated to various internal and external constituents throughout the slaughter, processing, distribution, retail, and home preparation segments of the farm-to-table continuum. Each must understand the food safety risks associated with their responsibilities in production, manufacture, distribution, preparation, and consumption. In the past, people understood the limits of science and technology in eliminating risk from raw and ready-to-eat meat and poultry. Even those products exposed to a pathogen kill step can be temperature abused in distribution or in preparation, causing risk of foodborne illness to re-emerge. Today, the need for education across the farm-to-table continuum is crucial. USDA must clearly communicate about risks, limits of present knowledge, and appropriate use of food safety interventions, behaviors, and practices. Prevention of foodborne illness is possible and achievable.

Recommendations:

Recommendations for research in risk analysis were made by each of the subcommittees. These recommendations were similar but differed in the specific techniques and applications associated with the three research areas. These recommendations can be summarized below.

(a) USDA should continue and strengthen its research on the development of techniques, concepts, and data that will allow accurate estimates of the impact applicable to changes in food production, preparation or regulation.

(b) USDA should continue to encourage agencies such as CDC to conduct research, surveillance and its subsequent analysis that will better characterize risks of foodborne pathogens and assist in the identification and characterization of high risk populations, particularly those with altered immune responses.

(c) USDA should undertake research on food safety risk communication to accurately determine current food safety knowledge and practice, capabilities of educational delivery and public information systems, and based on these research findings, implement needed improvements in risk communication programs.

HACCP

HACCP is a systems approach to identifying both the hazards associated with a food and the key steps that must be controlled to ensure the products safety (NACMCF, 1992). The three PRTF subcommittees each identified HACCP as a critical component of the Department's initiatives to control foodborne pathogens. They unanimously embraced the need to span the entire farm-to-table continuum, and concluded that USDA research will and must play a pivotal role in the Department's ability to implement HACCP.

Within the Live Animal segment, the overall thrust of HACCP-related research needs was the acquisition of knowledge necessary to allow commodity groups to develop and implement voluntary pathogen reduction quality assurance programs. Areas highlighted included the impact of farm management practices, development of potential intervention strategies, and the development of monitoring and verification techniques. In the area of Slaughter and Processing, the focus shifts to the acquisition of knowledge on the scientific basis for hazard analysis, CCP identification, establishment of critical limits, and methods for monitoring CCPs and verifying the HACCP system. Also accompanying the research that will assist the immediate implementation of HACCP was the identification of research needs in the areas of intervention development and microbial genetics and physiology that will serve as the basis for future improvements in HACCP systems. The emphasis of the Food Preparation and Consumption area also focused on the acquisition of the scientific data that will be needed to successfully identify the hazards and control mechanisms in retail and home food preparation arenas, as well as development of techniques for monitoring CCPs and verifying the efficacy of the system.

The primary recommendation associated with HACCP is that the agencies position themselves so that they can be prepared to respond in a timely manner to research needs that arise as HACCP is implemented. An intergral part of research direction toward HACCP should be the assessment of current intervention strategies and the development of new intervention technologies.

Public Health and Production Animal Surveillance and Monitoring

An integral part of any system for controlling foodborne disease is the acquisition of pertinent public health data. Timely public health surveillance information is critical for the identification of both new foodborne threats to public health and the reemergence of known foodborne pathogens. The continuity and reliability of measures of the incidence and extent of foodborne disease are needed to assess the effectiveness of pathogen reduction initiatives, as well as a necessary component of risk analyses. Similarly, monitoring and surveillance of animal production systems for human pathogens provides important epidemiologic data regarding actual and emerging pathogens.

Current Status:

The primary responsibility for acquisition and dissemination of information related to infectious disease statistics lies with CDC. Their primary involvement for the past 25 years has been through the National Disease Surveillance Program. This voluntary epidemiologic reporting systems requires state departments of health to notify CDC concerning the incidence of specific "reportable" diseases. This system, from which most foodborne disease statistics are derived, has a number of limitations. In particular, its passive nature leads to substantial under-reporting, and many foodborne pathogens are not among the reportable diseases. In addition to this program, CDC also acquires information on foodborne diseases through its program of providing assistance in epidemiological investigations of foodborne outbreaks at the request of state officials. In such instances, CDC often works in close coordination with regulatory agencies such as APHIS, FSIS and FDA. CDC periodically conducts active surveillance programs for selected pathogens, particularly when additional information is needed on emerging or reemerging pathogens. Two recent surveillance studies involve foodborne pathogens *Listeria monocytogenes* and *Campylobacter*. Additional programs on the incidence of human diseases (largely extraterritorial), particularly in relation to the emergence of new pathogens, are conducted by the Department of Defense. On the international level, statistics on foodborne disease are actively gathered by a number of countries (e.g., Canada, European Union) as well as by World Health Organization.

While USDA does not gather human health statistics, it does acquire data on the incidence of animal disease, some of which are potential pathogens in humans. For example, *Salmonella enteritidis*, phage type 4 is both a human and avian pathogen, and *Staphylococcus aureus* is a primary cause of mastitis in cows. Likewise, enterotoxigenic *E. coli* were primarily studied as a problem in piglets before it was realized that closely related strains caused gastroenteritis. More recently, *Arcobacter*, which was originally studied as a cause of abortions in production animals, has been associated with

gastroenteritis in humans. The National Animal Health Monitoring System (NAHMS) of APHIS provided the only known epidemiological study of *E. coli* O157:H7 in cattle and ground beef prior to human outbreaks in the Pacific Northwest. The ability to link our understanding of food safety in the farm-to-table continuum includes both human and animal monitoring and surveillance data collection and analysis.

Recommendations:

Most of the responsibility for public health surveillance is not within USDA but lies within the purview of HHS. As such, USDA is in the role of a user, not a provider. However, the Department should systematically provide HHS with a clear definition of our needs in this arena. The Department should maintain and strengthen its liaison with CDC, both through the presence of FSIS and APHIS personnel at CDC and the enrollment of USDA personnel in the EIS (Epidemic Intelligence Service) training program. It is recommended the Department request that when USDA employees are attending these training programs that they be assigned projects that are pertinent to food safety or other agriculturally related health concerns. CDC should also be encouraged to better estimate and characterize subpopulations that either have increased susceptibility to foodborne disease or that are at-risk for the chronic consequences of these infections (e.g. reactive arthritis). Both CDC and USDA need to collaborate on microbiological testing sensitivities and specificity so that comparisons can be made regarding pathogen monitoring and surveillance data collected from both animals and humans.

While USDA does not collect human health statistics, much of the large volume of regulatory and non-regulatory data that the Department routinely acquires on production animals could be potentially useful to better understand and forecast human foodborne disease. It is recommended that USDA establish and/or make available to responsible researchers, appropriate databases on pertinent animal pathogens and disease. Likewise, databases related to the incidence of foodborne pathogens in meat and poultry products could help establish relationships between public health and pathogen reduction strategies.

APPENDIX

APPENDIX A. Pathogen Reduction Research Summaries by Agency

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

The mission of Animal and Plant Health Inspection Service (APHIS) is to promote the health and well being of the peoples of the U.S. and its export customers through the administration of Federal laws and regulations in cooperation with State governments, pertaining to animal and plant health and quarantine, humane treatment of animals, the control and eradication of pests and diseases, and animal damage control. A relatively recent though increasingly important component of this mission is control of human pathogens that are harbored but do not cause disease in production animals. APHIS has been charged with the lead in Pathogen Reduction initiatives associated with live animals. These efforts are being integrated into the agency's existing Veterinary Services (VS) resources for conducting animal health surveillance, disease control, and eradication missions. VS involvement encompasses activities on the farm, during transport, and at livestock markets and auction. Expenditure for pathogen reduction research and related activities efforts totalled approximately $5,000,000 including $3,411,000 for *Salmonella enteritidis* control in eggs and poultry.

Resources available to APHIS include the VS National Veterinary Services laboratories. These facilities provide laboratory diagnostic services and conduct applied research. In addition, the APHIS VS Centers for Epidemiology and Animal Health (CEAH) have analytical epidemiologists, economists, statisticians, and others who support field operations and epidemiological projects.

APHIS has collaborative efforts with Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), the Food Safety and Inspection Services (FSIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). APHIS also has a scientist permanently stationed at the Center for Disease Control and Prevention (CDC) to act a liaison for joint epidemiological efforts. Some specific examples of research related activities either planned, underway, or completed are as follows:

- Acquired epidemiological data to determine the sources and prevalence of *E. coli* O157:H7 and other pathogens, and risk factors for cattle in regard to the role of meat composition, regional differences, imports, and consumption patterns.

- Evaluated the effects of management practices and health of dairy heifers to determine if a correlation exists. Herds were tested for *E. coli* O157:H7, *Salmonella enteritidis* and *Cryptosporidia*.

- Determined the prevalence of *Salmonella enteritidis* in layer flocks.

- Tested milk herds as a source of *E. coli* O157:H7, evaluated the risks associated with grazing on slurry fields and feeding ionophores, and tested the effectiveness of genetic fingerprinting to unequivocally identify *E. coli* O157:H7 sources.

- Funded research initiatives in probiotics, competitive exclusion and vaccines as potential means to prevent *E. coli* O157:H7 in cattle and *Salmonella enteritidis* in layer flocks.

- Evaluated management practices aimed at reducing the incidence of *Salmonella enteritidis* in layer flocks.

- Provided funds for the development of improved diagnostics for *Salmonella enteritidis* in flocks. This included research on ELISA techniques, lift assay of cultures of eggs, egg yolk antibody test, phage typing and plasmid analysis, and infection and transmission patterns from an infected flock.

- Conducted epidemiological field studies for risk assessment, risk analysis, control and intervention in layer flocks.

AGRICULTURAL MARKETING SERVICE (AMS)

The mission of the Agricultural Marketing Service (AMS) is to facilitate the domestic and international marketing and distribution of agricultural products, ensure fair trade practices, and assure the consumers of an abundant, high quality, and safe food supply. Although AMS does not have official research responsibilities, it does have a Memorandum of Understanding (MOU) with ARS for ARS researchers to work with AMS scientists to address AMS research needs. AMS also cooperates with other departmental agencies, OICD, FDA, and the Department of Defense.

AMS has Technical Service Laboratories in Illinois and North Carolina which provide support and contract services. Although AMS's primary research thrust have been directed toward egg and egg products, their interest and efforts in pathogen reduction are directed toward safety of poultry products. The agency also has responsibility for the microbiological quality of items purchased for school lunch programs. Some examples of AMS's research activities include:

- Conducted microbiological analysis to identify Critical Control Points in beef slaughter and processing facilities which produce raw patties. This baseline study was conducted for FSIS.

- Initiating a program to verify effective Quality Control laboratory programs.

- Funding and participating in a collaborative project with ARS and academic researchers to evaluate the effectiveness of current pasteurization treatments to destroy *Listeria monocytogenes* and *Salmonella enteritidis* in liquid eggs products.

AGRICULTURAL RESEARCH SERVICE (ARS)

As the Department's principle agency for conducting intramural research, the Agricultural Research Service (ARS) has a broad-based research program in food safety. This encompasses annually approximately $13,966,000 of projects that are directly related to pathogen reduction in meat, poultry and eggs. The majority of the agency's pathogen reduction research has been in response to research needs and requests of FSIS. More recently, there has been increased coordination and collaboration between ARS and both APHIS and AMS, as these agencies have become increasingly involved in food safety initiatives. ARS also has several collaborative initiatives with FDA.

Food safety research in ARS is conducted at a variety of locations throughout the country, reflecting different regional, commodity, and program orientations, as well as the need for specialized facilities and resources that are required to address the Department's research needs (e.g., animal production facilities, slaughter and processing pilot plants, isolation facilities). Major ARS food safety research locations include:

- National Animal Disease Center, Ames, IA (live animal and methods development research)

- Meat Animal Research Center, Clay Center, NE (live animal, slaughter operations, and methods development research)

- Southeast Poultry Research Laboratory, Athens, GA (live animal and methods development research)

- Food Animal Protection Research Laboratory, College Station, TX (live animal research)

- Russell Research Center, Athens, GA (live animal, slaughter and processing operations, and methods development research)

- Western Regional Research Center, Albany, CA (processing operations)

- Eastern Regional Research Center, Philadelphia, PA (slaughter and processing operations, methods development, risk analysis, and process development research)

The current research program encompass essentially all of the major laboratory-based research areas associated with the pathogen reduction needs including live animal or "pre-harvest" production activities, detection/quantitation methods development, slaughter plant activities, processing plant activities, risk assessment, and food service/retail activities, and basic microbial genetics and physiology. Specific examples of the research activities completed recently or currently underway include:

- Demonstrated that *Escherichia coli* O157:H7 infections in calves are asymptomatic.

- Demonstrated that while carcass washing helps reduce pathogen loads, it does not assure complete elimination of enteric pathogens.

- Successfully developed genetic probes, multiplex PCR assays, immunoassays, or other rapid methods based on the detection of specific genotypes/serotypes for *Campylobacter*, *Arcobacter*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Clostridium perfringens*.

- Developed immunomagnetic separation techniques to reduce the need for enrichment.

- Developing and evaluating a rapid analysis for determining gross contamination on carcasses which is based on bioluminescence technology.

- Demonstrated the potential for irradiation to control enteric pathogens, including *E. coli* O157:H7, in meat and poultry.

- Successfully demonstrated that competitive exclusion can help control *Salmonella* and *Campylobacter* in poultry flocks.

- Developing an on-line video-based system for the rapid detection of defective poultry carcasses.

- Demonstrated that the attachment of *Salmonella* to meat and poultry involves three mechanisms; adsorption, entrapment, and adhesion to collagen fibers.

- Demonstrated that water reuse can be successfully used in swine slaughter without adversely affecting microbial safety.

- Developed and provided in a user-friendly format, computer models for predicting pathogen growth and developing enhanced quantitative microbial risk assessments.

- Isolated, characterized, and demonstrated the efficacy of several bacteriocins that have activity against pathogens such as *L. monocytogenes*.

- Further characterized the cooling rate requirements for *Clostridium perfringens* under conditions that would occur in food service operations.

- Demonstrated that specific GRAS flavor compounds can reduce the thermal resistance of *Clostridium botulinum* and other foodborne pathogens.

- Demonstrated that chickens have increased susceptibility to *S. enteritidis* during molt.

- Currently developing methods and indicator tests for assessing the presence of human viruses in meat and poultry.

COOPERATIVE STATE RESEARCH SERVICE (CSRS)

As the Department's primary funder of extramural research, the Cooperative State Research Service (CSRS) makes research monies available through formula funds, Special Research Grants appropriated by Congress, and the National Research Initiative Competitive Grants Program. Formula funds include both Hatch and Evans-Allen funds that are provided to agricultural experiment stations at Land Grant and HBCU, respectively. Twenty-five percent of the Hatch funds are earmarked for cooperative research projects. Animal Health Formula Funds (Section 1433) are also allocated to Land Grant institutions. The formula funds are usually supplemented with other federal or non-federal monies. CSRS contributes about $4,380,000 million toward research projects dealing with pathogen reduction and control in meat and poultry. Many of these projects conducted by the agency's university partners also receive State and other public funds as well as private sector monies to support research. Live animal production or "pre-harvest" research efforts include identifying points and sources of contamination during food animal production and developing production management practice

to minimize introduction of pathogens into the food chain. Slaughter/processing research focuses on the pathogenesis of foodborne disease organisms, development of rapid and sensitive detection of techniques for pathogens, and development of new and improved technologies to control pathogens during slaughter, processing and distribution. Consumer related research includes research on risk assessment, consumer attitudes regarding food safety, and willingness to pay for improved food safety.

Two Special Grants administered by CSRS have direct involvement in microbiological food safety, the Food Safety Consortium (Universities of Arkansas, Kansas, and Iowa) and the Food Irradiation program (Iowa State University). Federal funding of these projects is approximately $1,500,000, with matching funds from State sources amounting to nearly $3 million. These programs support a broad range of specific food safety research projects.

The National Research Initiative (NRI) provides the USDA with a competitive grants mechanism through which it can target specific research areas for increased activity. Microbial food safety has been one of those areas, with approximately $2,200,000 being provided annually to support basic research that will develop the knowledge needed to control foodborne pathogens. Research that has been funded have included laboratory-based projects in live animal (pre-harvest), processing/slaughter, and food preparation. This includes projects investigating pathogenicity and virulence, pathogen physiology and genetics, methods development, intervention strategies, and novel control approaches.

Specific examples of the research currently underway and funded or administered by CSRS programs include:

- Evaluating potential for developing vaccines and competitive exclusion cultures for controlling foodborne pathogens in production animals.

- Identification and characterization of bacteriocins for controlling *L. monocytogenes*, *Salmonella*, and other foodborne pathogens.

- Evaluating potential for development of slaughter interventions such as organic acid washes, UV-light treatment, lactoperoxidase treatment, etc., to control *Salmonella*, *Listeria*, and *Campylobacter*.

- Identifying genetic factors associated with the attachment of *Salmonella*.

- Identification of factors influencing the consumers perceptions of food safety risks and the impact it has on purchasing patterns.

- Determining the physiological basis for psychrotrophic growth of *L. monocytogenes*.

- Elucidating the role of cell surface components as virulence determinants for *Salmonella*.

- Developing of rapid methods and biosensors for the detection of *Campylobacter*, *Salmonella*, *L. monocytogenes*, *Bacillus cereus*, and foodborne viruses.

- Assessing of the impact of packaging systems on growth and toxigenesis of *Staphylococcus aureus*.

- Determining the thermal resistance of *E. coli* O157:H7 in food service operations.

ECONOMIC RESEARCH SERVICE (ERS)

The USDA Economic Research Service (ERS) provides the Department with the economic research and related social science analyses that are needed to determine the impact of its initiatives. ERS has had a long standing involvement in assessing both the economic impact of foodborne disease and the effect that regulatory initiatives are likely to have on both industry and society at large. This includes projects in support or collaboration with FSIS, ARS, AMS, FDA, APHIS, and CDC. Current resources allocated for analysis pathogen reduction activities and related food safety issues total approximately $700,000.

Current or recent activities include:

- Assessed the industrial structure and organization of the meat and poultry slaughter/processing industry.

- Evaluated the economic impact of food safety regulations, including effects of advanced meat separation technologies and mail order meat transactions, and costs of HACCP implementation.

- Estimated the medical and loss of productivity costs of foodborne salmonellosis, listeriosis, congenital toxoplasmosis, campylobacteriosis, and *E. coli* O157:H7 infections.

- Analyzed the Human Nutrition Information Services' (HNIS) Diet and Health Knowledge Survey and FDA consumer surveys on food safety perceptions and development of new methodologies for assessing consumer perception and valuation.

- Analyzed the "cost-of-illness" of Guillain-Barre syndrome cases caused by *Campylobacter*.

- Estimated the farm costs associated with control of *Salmonella enteritidis*.

EXTENSION SERVICE (ES)

While the Department has multiple means for passing on food safety information, the primary agency charged providing information, education, and problem-solving programs is the Extension Service (ES). While ES does not have a research mission *per se*, through the Cooperative Extension System, it does:

- design, implement, and evaluate education programs to improve the ability of all components of the food system (producers, processors, food handlers, consumers, etc.),

- evaluate educational programs and demonstrate effective methods of food safety education, and

- provide feedback mechanisms to the research community.

The primary means of achieving their goal is through the development of models programs and workshops. It is difficult to get an accurate estimate of the total monies allocated to extension efforts due to the collaborative Federal/State/Local/University nature of the Cooperative Extension System. However, current estimates indicate that at least $990,000 are currently being used for educational and related initiatives. Examples of current activities include:

- Developing model training programs for food handlers.

- Conducted a national workshop for cooperative extension system food safety educators.

- Developing of curricula for HACCP education for plant personnel.

- Establishing a demonstration project for development of a on-farm HACCP for broiler production.

FOOD SAFETY AND INSPECTION SERVICE (FSIS)

The USDA's FSIS is charged with protecting the public by ensuring that meat and poultry products are safe, wholesome and accurately labeled. In the food safety arena, FSIS encourages, supports, and conducts studies needed to understand the scientific basis for an inspection program to protect the public. Consequently, the agency has been charged with the lead in pathogen reduction initiatives related to slaughter and processing of meat and poultry, as well as activities associated with the food preparation and consumption area.

Approximately $8 million has been allocated for Pathogen Reduction research. FSIS' Technical Services Laboratories in Alameda, CA, Athens, GA, and St. Louis, MO provide analytical and research support for pathogen reduction efforts, with additional specialized facilities available at Methods Development Laboratory at Beltsville, MD for the evaluation, development, improvement, and adaptation of methods for field use. FSIS' Science and Technology Division contains expertise in statistics, microbiology, chemistry, and related disciplines for the development and assessment of research plans, experimental design and analysis, data analysis, and related activities. Other pathogen reduction research identified by FSIS is conducted in collaboration with ARS, CSRS, AMS, and other sources, such as the Food Safety Consortium. Additional collaborative efforts have been undertaken with ES, APHIS, ERS, and other agencies and departments, such as CDC and the FDA. This includes the permanent stationing of a FSIS scientist at CDC to serve as a liaison for epidemiological investigations. FSIS also provides research funds in the form of research contracts to meet specific research needs, particularly in the area of diagnostic methods development.

Some specific examples of pathogen reduction research and related activities either planned, underway or completed are cited below.

- Conducting comprehensive microbiological surveys of cows and bulls, steers and heifers, disabled cows, broiler chickens, market hogs, turkeys and retail ground beef to obtain a microbiological profile of these 'commodities'.

- Supported research contracts to characterize pathogenic bacteria so that the most effective interventions to reduce pathogens are used along the food chain continuum.

- Working in collaboration with ARS to establish time/temperature requirements to reduce bacterial proliferation in ground meat and meat trimmings.

- Evaluated the effectiveness of approved anti-microbial agents (TSP, organic acid sprays) to reduce bacterial load.

- Developing and evaluating rapid microbiological methods for laboratory and in-plant use. Some of the evaluated technologies include antibody coated beads, antibody coated dipsticks, ELISA techniques, automated systems, DNA probes, PCR tests, immunoassays for bacterial toxins, test kits that can used to evaluate sanitation effectiveness, adaption of kits to plant facilities, and rapid test kits for pathogens.

- Evaluate the feasibility of incorporating microbiological testing on product contact surfaces of equipment in conjunction with visual inspection for monitoring sanitation programs in meat and poultry plants and for monitoring of Critical Control Points (CCPs).

- Evaluating changes in processing procedures, such as trimming vs washing and dehairing hides to reduce bacterial load.

- Developing quantitative risk assessment methodology for application to decision making on pathogen reduction strategies as applied to meat and poultry production practices.

- Determining what record keeping in inspected plants is needed to support traceback to specific animals being slaughtered and finished lots traced back to specific meat and non-meat ingredients.

- Conducted focus group research on effectiveness of alternative presentations of safe-handling information and conducted a campaign to promote public awareness.

- Developing and assessing of educational programs and curricula for consumers, food service personnel, and others involved in retail operations.

- Conducting surveys, in conjunction with FDA, on consumer food handling knowledge and practices.

PACKERS AND STOCKYARDS ADMINISTRATION (PSA)

The Packers and Stockyards Administration (PSA) is responsible for administering the provisions of the Packers and Stockyards Act of 1921. The mission of PSA is to promote fair business practices and a competitive marketing environment for the marketing of livestock, meat and poultry. Though the principal function is not research, PSA's does have associated Pathogen Reduction efforts valued at approximately $492,000 for FY94. PSA programs that support or augment research initiatives include:

- Reviewing of all stockyards to determine if services, facilities, and handling procedures are adequate to provide prompt and reasonable care to minimize risk of injury, death, or other avoidable loss and cross contamination.

- Establishing requirements for full disclosure of all transactions and record keeping and will set forth guidelines for compliance.

APPENDIX B. Live Animal Subcommittee Research Areas and Researchable Questions

The Live Animal area consists of activities dealing with on-farm management and husbandry practices, transportation of live animals, and marketing prior to the arrival of animals at the slaughter establishment. The objectives of the subcommittee were to identify research areas and researchable questions, prioritize research areas, and identify researchable questions as immediate (less than one year), short term (within two years), and long term (more than two years) goals.

Ecology and Epidemiology

Epidemiology is the study of disease in relation to populations and ecology is the study of populations in relation to their environment. The contribution of both of these sciences is indispensable to the development of live animal production practices that can improve food safety at the consumption level. The frequency and distribution of pathogens (in this case the specific etiological agents of foodborne human illness) can be estimated by observational epidemiological studies. Differences in these estimates from population to population and environment to environment can result in the generation of hypotheses. These hypotheses will include possible effects of host factors such as species, breed, sex, and age, and environmental factors such as husbandry, feeding, climate, shipping, exposure to vectors, reservoirs and carriers. These hypotheses can be treated by experimental epidemiological studies and the results used to design effective pathogen reduction strategies where indicated.

1. What improvements in diagnostic techniques are required for effective detection of known and emerging human pathogens in live animals?

Diagnostic tests are essential to conducting ecological and epidemiological studies in two ways. First, they provide for the detection of asymptomatic infection in populations such as herds or flocks. This enables the estimation of the proportion of involved subpopulations and identifies those subpopulations with infected individuals. Next, they provide for the estimation of the number of individuals within each subpopulation that are infected. Depending on their specificity and sensitivity, adequate tests may already exist for the detection of many of the specific etiological agents of foodborne illness at the herd or flock level and we need only develop the applications of these tests. More sensitive and more rapid tests are needed for the identification of individually infected animals within these subpopulations. Initial epidemiologic studies might be able to make use of existing data if active reporting could be encouraged and passive reporting systems improved.

- Immediate: Improvements in reporting procedures; Validation of currently available tests
- Short-term: Immunological, chemical, and/or physical tests (elimination or reduction of enrichment process)
- Long-term: Rapid tests for on-farm/transport use; Sampling improvements; Innovative technology

2. What is the ecology of the pathogen in the production environment?

This information, especially the temporal component, is essential to the identification of critical control points and the practical interventions that can be made at those points to reduce or eliminate the specific etiologic agents of foodborne human illness. Observed differences in the distribution and frequency of the agent between populations and between environments can indicate studies that may elucidate the mechanisms of survival and spread. We can then test various management options, such as reducing stress, that will interrupt the transmission of or limit the persistence of the agent.

- Short-term: Pathogen sources (reservoirs, fomites, vectors)
- Long-term: Sentinel animal/organism identification; Pathogen/source relationship; Pathogen/environment relationship; Transmission dynamics (how? when? where?)

3. What is the role of the asymptomatic carrier in the transmission of human disease?

The healthy food animal harboring human health pathogens may be an asymptomatic carrier of foodborne disease. It is important, therefore, to understand the role of an asymptomatic carrier in human foodborne illness if we are to design methods to reduce possible risks associated with these animals.

- Immediate: Potential carrier identification
- Long-term: Pathogen/carrier relationships; Strategies for carrier elimination

4. What epidemiological data are required to identify sources of human disease associated with animal production and to identify factors that contribute to the prevalence and distribution of that pathogen?

Answering this question will require very close collaboration between the epidemiologists investigating foodborne illness, public health epidemiologists, and those attempting to identify the critical control points that can be used in the live animal production environment. It will also require the implementation of the diagnostic tests (that we have referred to) in elucidating the distribution and frequency of the specific etiologic agent in the source herds and flocks. It is from this data we will develop intervention strategies that will be tested at the live animal stage of food production.

- Immediate/Short-term: National prevalence of pathogens in certain slaughter classes just prior to slaughter (specific to season and geographic locality)

- Long-term: National prevalence of pathogens in each slaughter class at each link of the live animal marketing process (specific to season and geographic locality); Correlation of national prevalence of pathogens through all links of the food chain; Dynamics of acquisition/transmission; Correlation of animal to human disease process and vice versa

Pathogenicity/Virulence/Microbial Physiology/Genetics

1. How does the human pathogen colonize and maintain itself in a production animal?

The first requirement for developing realistic intervention strategies is a fundamental understanding of the ways that pathogens can colonize the gastrointestinal (GI) tracts of food animals. The interaction between the surfaces of the pathogen and the GI tract that allow attachment and growth are of paramount importance. Further information on the minimal requirements for pathogen survival and growth could have many implications. Since the GI tract is normally inhabited by beneficial and non-pathogenic bacteria, the role of microbial competition in the GI tract and its effect on the pathogen needs assessment. This information is particularly important in the concept of competitive exclusion to prevent colonization by pathogens. This research can be accomplished in the short-term in poultry. In other animals, it is long-term due to the lack of research in this area..

- Short-term: Pathogen growth requirements; Attachment mechanisms; Pathogen resistance/survival characteristics

- Long-term: Pathogen/competing microflora relationships; Animal/pathogen relationships

2. What information or techniques are required to support development of improved diagnostic tests that can distinguish strains that are pathogenic and non-pathogenic to humans?

As previously mentioned, existing information indicates that most of the foodborne pathogens that cause disease in humans do not cause equivalent illnesses or disease in food animals. This finding could be due to a variety of microbial characteristics including attachment, colonization ability, toxin production, and other virulence factors. Essential to a linkage of human pathogens to food animal sources is the genetic characterization of the pathogens in humans and animals and a comparison of the two. Long-term requirements for improved testing should rely on the physiology of the pathogen in animals and humans.

- Short-term: Human and animal pathogen characterization and comparison; Virulence factors; Use of animal models

- Long-term: Test method development

3. What information is needed about animal and microorganism interaction to develop new strategies for preventing or eliminating colonization by the organism?

A food animal and its attendant microorganisms live in equilibrium. It is known that shipping stress and some other environmental changes can effect certain pathogen colonization and shedding in the animal. The immune status of the food animal can also be affected by these same influences. Intervention strategies may be developed with more information about the food animal immune system and how it affects the host-pathogen interactions.

- Short-term: Effects of stress; Effects of environment

- Long-term: Immune modulation; Animal/pathogen relationships

<u>Live Animal Production ("Pre-harvest") HACCP</u>

There is a need to expand the effective use of HACCP principles to allow its implementation in the pre-harvest environment. To achieve this goal, there are several deficiencies in knowledge that need to be addressed through USDA research programs.

1. What information is needed for an understanding of the impact of good production practices on the potential for production animals to serve as a source of human disease?

A diversity of production, marketing, and transportation practices are being used today in the livestock industry. Identification and compilation of these practices, combined with monitoring trend analysis and available microbial baseline studies in livestock and poultry, are immediate needs to provide the foundation for establishing pre-harvest HACCP programs. Once established, these HACCP programs can be enhanced through acquisition and analysis of additional microbiological baseline data, and evaluation of marketing practices. HACCP plans can be further optimized by long term research on production factors such as feed withdrawal, waste management, feed additives, etc.

- Immediate: Compilation of current production practices; Compilation of current transportation and marketing practices

- Short-term: Production and marketing trend analysis; Microbial baseline in live animals (species specific); Pathogen levels/transportation and marketing practices relationships (truck washing, auctions, terminal markets, dealers, etc.)

- Long-term: Pathogen levels/production practices relationships (waste management, feed withdrawal, use of ionophores, etc.)

2. What improved or alternate intervention strategies are required that can be used to prevent or control human pathogens in production animals?

One key to HACCP implementation is the identification of effective interventions. Current intervention strategies need to be evaluated and effective ones implemented in the short term to identify means for optimizing their effectiveness. This should be integrated with longer term research on new intervention techniques, especially ones that have promise of adding value to the products. Value added interventions offer the advantage of being producer motivated, and thus more efficient and likely to be accepted.

- Short-term: Pilot testing of current intervention strategies

- Long-term: Innovative interventions

3. What techniques need to be developed to implement, monitor, and validate pre-harvest HACCP programs?

Implementation of HACCP-based programs in the live animal sector of the food chain offers promise in the reduction of foodborne pathogens and for adding value to the product. Existing quality assurance programs in production and transportation operations should harmonize with

the HACCP concept. An immediate need is the ability to identify critical control points and provide methods for monitoring and validation. Once pre-harvest HACCP programs have been established, long-term research can be targeted to the development of improved methods for monitoring and verification.

- Immediate: Methods for monitoring critical control points
- Short-term: Risk factor identification; monitoring CCPs
- Long-term: Verification procedures and implementation; Improvements of monitoring and verification procedures

Economic Analysis/Risk Assessment

The cost/benefit of HACCP interventions must be evaluated on multiple production levels and for multiple timeframes. Based on existing knowledge, large integrated companies could have HACCP programs in place from production through processing and marketing. USDA has emphasized rural revitalization and development, which stresses the importance of small, and/or organic and/or other types of "family" farms. These types of farm operations are less likely to implement HACCP programs readily.

1. What is the cost/benefit of HACCP interventions?

HACCP intervention or pre-harvest programs must include an economic analysis of the effect of any mandatory programs relative to farm size. If the effect of HACCP programs is to reduce the ability of these operations to stay in business, educational programs should be researched that would allow these farmers to form cooperatives or find other mechanisms to comply with regulations and remain viable. All cost/benefit analyses should include short term research on the compatibility of HACCP with existing production practices, plus realistic and scientific industry and societal cost estimates of HACCP programs. Longer term projects include the HACCP intervention and subsequent food safety risk relationships, and cost estimates of foodborne diseases.

- Short-term: Compatibility with existing production practices (including all production methods and sizes); Realistic cost estimates of HACCP (national and international)
- Long-term: HACCP intervention/risk relationships; Scientific based cost estimates of foodborne diseases

2. What statistical and epidemiological techniques are required in order to be able to extrapolate the detection of a pathogen on a limited number of farms to a realistic estimate of disease transmission/exposure on a national basis?

Due to the wide diversity in the approaches and localities for rearing production animals, the logistics and economics of assessing the incidence of human pathogens make it virtually impossible to acquire more than a "snapshot" of the role of live animals as a source. This is compounded by the lack of overt symptoms in the animals, the general low incidences of occurrence, and the heterogeneous distribution within herds. This mandates that effective sampling designs and complimentary statistical and epidemiological techniques be available so that critical factors can be identified with assurance. This requires a long term research effort be initiated to evaluate the effectiveness of current statistical methods to estimate the extent of live animal food safety concerns on a national basis and to develop new techniques to overcome identified deficiencies.

3. How can existing risk assessment models for animal disease be expanded to include human pathogens?

The development of effective risk assessment models is dependent on establishing dose-response relationships and estimating the extent of exposure. However, direct experimentation with humans is difficult and in many instances impractical. There is a need for long range research directed toward determining how data and risk assessment techniques for animal diseases can be used to enhance microbial risk assessments for human disease. One such area is determining the potential for expanding or modifying current risk assessment models for animal disease to include human pathogens. A second is identifying and evaluating the effectiveness of animal models to acquire dose-response data and models. Linking public health and animal based monitoring and surveillance programs also provide long term necessary data.

<u>Risk Communication/Technology Transfer</u>

Risk communication may be the intrinsic key to the success of any food safety program. Even the finest, most valid technical information will have little effect on the public perception of the relevant factors unless the information is made available in a form that is readily understandable.

1. What is the information needed, both to and from, the different target populations (consumers, producers, regulatory agencies, Congress)?

A basic understanding of the principles of risk related to the effects of pathogens on food safety needs to be shared with and by the target populations. This encompasses additional efforts to foster, stimulate, and promote an open forum between all affected parties. It also means that

technical information must not be closeted, but distributed as widely as possible (including freely accessible electronic systems). The value of this policy will be realized in the confidence of the producers and consumers in food safety. The validity of the information upon which risk analysis is based also will be stimulated by this policy of openness. This program can help to demonstrate the usefulness of risk communication becoming ingrained as a standard for effective federal programs.

- Short-term: Evaluation process; Public and producer perceptions

- Long-term: Behavior modification (knowledge, skills, and abilities)

2. How do you deliver the information to the target populations in the most efficient manner?

In the earliest collection or development of technical information about food safety, risk communication is essential. From the beginning, the information needs to be stated clearly, in the simplest terms, and shared with the target populations. Also, during the developmental stages is the time to consider necessary security of information. Sensitive information that is subject to mistaken perception by producers or consumers need to be restated in ways that will enhance its use. Limitations of participation in risk management decisions need to be clearly stated at the outset.

It is important to stress the form and format of communications at least as much as the method or technology used to accomplish it. The media, including news and trade publishers, managers of interactive electronic systems, Extension educators, regulation proposers, and field personnel are all efficient ways to exchange information. The importance of clear, concise, factual information that will positively affect public perception is critical to effective communication. Participating organizations will have a chance to understand the basis for action and to determine for themselves the degree to which the risk decision and the associated risk message are based.

Suggested specific information and opinion exchange methods are: citizen advisory groups, representative sample surveys, regularly published updates, newsletters, briefings, focus groups, independent preview and review, "white papers", advocacy groups, state and local community groups, town meetings, on line data bases, interactive computer networks, video tapes, and public announcements. We must maintain the two way nature of these communication systems.

- Short-term: Evaluation process; Security of information; Public perception

- Long term: Maintaining communication

Traceback

When foodborne human illness outbreaks occur, the ability to traceback to the farm is a valuable tool for on-farm field studies. However, sufficient information does not exist to detect and prevent the introduction and growth of human pathogens in the live animal, making it difficult to devise prevention strategies. As a result the Live Animal Subcommittee chose to rank the Traceback category as its last priority research area.

1. What existing technologies can be expanded or consolidated to improve traceback capabilities?

Currently, there are a number of USDA agencies (AMS, APHIS, FSIS, P&SA) that require identification of live animals, carcasses, and slaughtering/processing plants for regulatory and information gathering purposes. This researchable question was incorporated into the Traceback category for the purpose of examining what can currently be accomplished using existing traceback methods and to identify the gaps in these existing methods. Information regarding identification technologies from USDA agencies must be consolidated in order to evaluate the effectiveness of, and improve existing technologies. It is estimated that this can be accomplished within one year.

- Short-term: Efficient systems for data management; Animal identification retention; Reading and recording systems; Electronic identification

- Long-term: Value additions e.g., animal health parameters

2. What alternate technologies, such as "genetic fingerprinting", could be developed to identify unequivocally the identity of an animal and the products derived from it?

Existing identification methods do not allow traceback of a meat or poultry product to a specific live animal. Development of alternate technology could allow for positive identification without the introduction of non-food components (e.g., physical or electronic ear tags, back tags, etc.) in food systems.

- Long-term: Cost estimates; Reliability; Data Management; Producer acceptance

3. How can current technologies be modified to overcome concerns related to the introduction of non-food components in a food system?

Electronic traceback technologies currently exist. However, FDA regulations do not allow for the introduction of non-food items, such as a computer chip, into the food chain.

- Short-term: Standardization of electronic identification devices and readers

APPENDIX C. Slaughter and Processing Subcommittee Research Areas and Researchable Questions

The Slaughter and Processing area consists of in-plant slaughter activities, in-plant processing activities and distribution and transportation of raw and finished products. This subcommittee also considered certain retail operations because pathogen reduction activities in these retail operations are comparable to those found in in-plant processing activities. The objectives of the subcommittee were to identify research areas and researchable questions, prioritize research areas, and identify researchable questions as immediate (less than one year), short term (within two years), and long term (more than two years) goals.

Prevalence/Incidence/Sources

1. What methods for sampling and detection of foodborne pathogens exist and how can they be improved or replaced with new techniques?

There is a need to improve on existing techniques for detection to make them faster and more user-friendly. One simple improvement could be elimination of an enrichment step. Consequently, we need innovation and greater refinement of current detection techniques. Any new technique(s) must pass certain criteria for accuracy, precision, safety, ease of use, durability and cost effectiveness. Real time detection methodology is needed. Several new technologies based on DNA and mRNA have been developed and shown to be effective. There is a demand to adapt these new detection technologies to the slaughter/processing environment. In the development of new technology for detection, we must consider how we sample for the pathogen and develop improved sampling methods. Improving existing detection methods has been identified as accomplishable in the short-term while development of new detection methods is a long-term objective.

2. What are the levels and sources of pathogenic bacteria in meat and poultry products at various stages along the food chain continuum?

Surveys of the level of pathogens, their points of entry and their source(s) in the slaughter/processing environment and periodic reassessment and re-evaluation is needed. To understand changes of microbial environment in the slaughter/processing facilities, it is essential to have a means for assessing the impact of such changes that might occur in ingredient sources, formulations, transportation/distribution, warehousing and stock rotation practices. In particular, what role does transportation and distribution play in pathogen levels, cross-contamination and as a reservoir of pathogens? Are the current requirements for cleaning cargo containers or restricted usage of cargo containers sufficient or are they needed? An important aspect of pathogen cross-contamination of food is where it occurs, by whom, by what process and to what

extent does it occur. Surveys can be accomplished in the short-term while periodic reassessment is a long-term initiative.

3. How do we evaluate and assess the likely impact of changing slaughter/processing procedures on prevalence, level and sources?

Change in how we slaughter and process meat and poultry needs to be explored and evaluated. For instance, is hide removal necessary or is the manner in which we remove the hide important in pathogen reduction? In the short-term, we need to assess current practices; however, we also need to examine new and possibly different ways to slaughter and process in light of a need to develop practices that will reduce or control the level of pathogens on meat and poultry products.

Microbial Physiology/Ecology

1. What effects do various physical and chemical parameters have on bacterial survival and growth?

To increase the safety and stability of meat and poultry products, there is a need to better understand the interaction of physical and chemical parameters on bacterial survival, growth rate, and activity. The development of predictive models using both extrinsic and intrinsic factors such as required nutrients, moisture, temperature, pH, competitive microflora or chemical inhibitors could be used to determine relative food safety risks and hazards. Development and assessment of parameter effects are long term research products.

2. What are the mechanisms of bacterial attachment/detachment to tissues? To processing equipment? Can these mechanisms be disrupted to enhance removal of the bacteria?

During the skinning and evisceration operations of meat and poultry processing, the carcasses may be exposed to numerous foodborne pathogens. The entrapment of bacteria in skin channels and muscle tissue increases as the carcasses are further processed. Current research indicates rinsing with organic acid sprays and other aids only remove a small amount of the bacterial pathogens that may be present. *Salmonella* spp. and *Campylobacter* spp. affix themselves so tightly to the muscle tissue by adhesion, entrapment and absorption that they become part of food intended for human consumption. Research investigating how bacterial pathogens attach to food and equipment surfaces is important to the development of procedures to release cells or prohibit their attachment. This research has been classified as long term.

3. What knowledge of microbial physiology and genetics is needed to provide a basis for new developments for the detection and control of pathogenic microorganisms?

Current procedures for the isolation and quantification of foodborne pathogens and their toxins in meat and poultry products are not always reliable and often too slow. In many cases, the products tested are already in the marketplace before the results are available. In addition, many of these procedures cannot be used for field application or in-plant monitoring due to the fear of reintroducing bacterial pathogens into a processing environment by way of the enrichment step. Online, real-time methods do not exist.

With recent advances in biotechnology have come rapid, sensitive, and inexpensive techniques based on immunological and recombinant DNA principles, some of which can be applied in the Slaughter/Processing part of the meat and poultry continuum. These tests usually require little operator skill and yet can be sensitive and precise. Innovative tests, such as enzyme-linked immunosorbent assay (ELISA), immunocapture systems and polymerase chain reaction technology/DNA probes, have been developed as alternatives to classical microbiological procedures. The evaluation of these techniques for meat and poultry products will require extensive research. Such improved methods are needed to further our understanding of the ecology of foodborne pathogens, the epidemiology of foodborne disease and the critical control points in an HACCP system and are considered long term efforts.

Slaughter/Processing HACCP

The Slaughter/Processing Subcommittee recognizes the need for an improved inspection system based on HACCP principles. HACCP is a prevention-oriented process dependent upon the application of controls at critical points along the slaughter/processing continuum. The Subcommittee defined this continuum to include antemortem, slaughter, processing, warehousing, and distribution through the allied industries. The development of proper implementation, evaluation, and validation techniques will play an integral role in the success of any HACCP program.

1. What is the scientific basis for identifying hazards associated with meat and poultry products and establishing critical control points and critical limits?

In order to implement a successful HACCP program, scientifically based information must be obtained regarding the sources, transmission, and detection of pathogens. In addition, initial levels of pathogens in live animals and their products must be determined in order to measure reductions in levels and evaluate whether or not significant reductions have been achieved.

The identification of hazards in the current slaughter/processing continuum can be accomplished within the "Immediate" timeframe. It is the opinion of the Subcommittee that the acquisition of the knowledge necessary to measure the impact of pathogen reduction resulting from the change

to a HACCP system will be "Short Term." Periodic review and modifications of the HACCP system will be on-going and "Long Term."

2. What methods for monitoring critical control points or verifying HACCP operations are effective in relation to sensitivity/accuracy, cost, timeliness, ease-of-use, etc.?

Various industries currently have HACCP processes in place which could be evaluated within the "Short Term" timeframe for adaptation in the slaughter/processing continuum. Are all hazards and critical control points comprehensively identified? In addition, "generic" HACCP models are currently in place for some classes of livestock. HACCP systems for the slaughter/processing continuum will have to be developed and modified so that they are species/class and facility specific. The continued development, on-going updating, and improvement of HACCP methods as scientific knowledge becomes available is considered to be a "Long Term" research priority. Continuous validation of HACCP systems in place is a necessary component of any successful process and will be on-going.

In conclusion, the goal envisioned by the subcommittee for HACCP is to permit industry to improve food production methods, so that fresh meat and poultry products are delivered "pathogen safe" and ready-to-eat products are delivered "pathogen-free", to the retail segment of the farm-to-table continuum.

<u>Technology Development and Transfer</u>

Even with improved sanitation and the best slaughter and dressing techniques, it may not be possible to eliminate all pathogenic microorganisms from meat and poultry being processed. Therefore, USDA must effectively employ existing technologies and develop new technologies to break the chain of microbial contamination on meat and poultry products and thus reduce the chances that pathogens will be on or in those products.

1. What current technologies exist or need to be developed to control or reduce pathogens? How can these technologies be adapted to food operations?

Intervention technologies can employ biological, physical, or chemical interventions to accomplish the desired goal. Immediate and short term efforts should include the evaluation, adaptation, or improvement of existing technologies. Long term efforts should focus on the development and evaluation of new intervention technologies.

The primary researchable question about biological interventions has both short term and long term goals. In the short term, what is the impact of currently available microbial inhibitors or bacteriocins on the growth and survival of pathogens? In the long term, are there new or

alternative antimicrobials (e.g., bacteriocins) that can be used to control the growth or survival of pathogens in meat and poultry products?

There are several questions about physical intervention technologies, such as ohmic heating, surface pasteurization, or hydrostatic pressure. Two questions can be immediately addressed: is rinsing of contaminated meat as effective as trimming for the removal of pathogenic bacteria?; and are there simple means available to evaluate the efficacy of rinsing carcasses? Short term research should address the following questions: can chilling technologies be improved to decrease the time needed to achieve inhibitory temperatures and eliminate cross-contamination (e.g. are there alternatives to immersion scalding and immersion chilling steps for poultry slaughter?) What is the impact of water reuse in slaughter and processing operations on the microbiological safety of meat and poultry products?; and can equipment and process-line designs be modified to increase their effectiveness in controlling pathogens? The last question also may require long term research depending on the technologies explored. Other long term questions are: are there new packaging materials or different packaging conformations (e.g., shapes or sizes) that could reduce the load or frequency of pathogens on meat or poultry products?; and are there new or improved modified atmosphere packaging conditions to accomplish the same goal?

There are also several questions about chemical interventions to be addressed immediately: do bacteriocidal wash treatments provide an effective means of reducing pathogen levels in final products?; what other disinfectant technologies are available as rapid alternatives if chlorine use is banned or limited in food unit operations?; and are those alternatives effective, safe, cost efficient, and easy to use?

In the long term one additional question is researchable: are there new food additives or new uses of existing food additives that could be employed to inhibit or control bacterial growth and survival in food products?

2. What currently available models are effective for assisting in setting critical limits, disposition of product produced under conditions of process deviation and assessing the effects of variables (process temp., etc.)?

Pathogenic microorganisms frequently are not found in the slaughter or processing environment in sufficient numbers or with sufficient frequency to determine the behavior of microorganisms in meat or poultry products under real conditions. Expert or "smart" systems for modeling the behavior of microorganisms under simulated conditions are needed to assist in setting critical limits, in disposing of product processed under conditions of process deviation, or in assessing the effects of process variables on microbial behavior.

The short term researchable question is: are there existing systems that can be modified to effectively simulate conditions in products under real processing circumstances? In the long term, are there new, improved systems that could be developed to better meet our pathogen reduction needs?

3. How can technology transfer between industry, government, and academia be enhanced?

Ultimately, technology transfer between government, industry, and academia must be employed to accomplish the desired goals. While there is some cooperation among those groups, the technology transfer process must be improved to obtain the best results. The question is how can technology transfer among the groups be enhanced to provide the best opportunity for pathogen reduction in the slaughter and processing areas. These initiatives could be considered short to long term .

Economic Analysis and Risk Assessment

1. How can mathematical models be used to predict the behavior of pathogenic microorganisms in meat and poultry products?

Predictive microbiology uses mathematical modeling techniques to describe the behavior of microorganisms in foods. These techniques have the potential of providing inspectional personnel with a rapid means of objectively predicting the likely behavior of pathogens in meat and poultry products. An immediate need is to validate currently available models by assessing their accuracy and effectiveness in a number of meat and poultry products, and assessing their potential for aiding in the establishment of HACCP programs including identifying critical control points, establishing critical limits, and deciding the disposition of product produced under process deviations. A short term need is to identify what additional factors (e.g., effect of transitory temperature abuse, acidulant identity) have to be addressed to provide more effective models that will assist inspectional efforts. This can then be used to initiate a more long term effort to acquire the data needed to develop the expanded models and application systems such as "process simulations" and "expert systems" that would provide the models in a user-friendly format. A related long term need is the development of techniques for integrating dose-response and predictive microbiology models. This is the key to being able to conduct quantitative microbiological risk assessments.

2. What assessment techniques can be developed to assist in the objective evaluation of the likely impact of changes in slaughter or processing operations or regulations?

A long term research effort is needed to develop advanced "process simulations" that integrate both risk assessment and economic models. This capability is needed to objectively estimate the

likely effects that changes in meat and poultry slaughter and processing, including pathogen reduction strategies, would be expected to have on public health and economic impact. Provided in a user-friendly format, models of this type would provide policy makers, as well as the meat and poultry industry, with a tool to assist them in optimizing pathogen reduction efforts.

3. What are the costs and benefits of education versus other regulatory interventions (compliance) for protecting "at-risk" or high-risk populations?

While education is a relatively inexpensive intervention for regulators, it imposes costs on producers and processors to change their behavior. Other regulatory options may have a higher benefit/cost ratio or have higher net social benefits. Such options for reducing risks to high-risk subpopulations should be evaluated such as certifying methods to produce reduced pathogen foods which could be identified with special labels and can be expected to command a premium price.

Risk Communication and Education

1. What resources and techniques need to be available to train industry, federal, state, and local regulators in the concepts and practices of HACCP?

In the risk communication and education area, the principal questions focus on identifying knowledge and information that must be communicated to various internal and external constituents throughout the slaughter, processing, and distribution segments of the farm-to-table continuum. First among these is the need to assure that resources and techniques are available to train industry personnel and regulators on the concepts and practices of HACCP. Such training is more than a "how-to" approach. Implementation of HACCP requires a fundamental change of thinking for the industry about the nature and comprehensiveness of manufacturing controls and responsibilities to assure food safety. For inspection officials, it also represents a significant departure from current ways of regulating industry activities. Different types of knowledge, skills, and abilities are needed by regulators to verify the effectiveness of HACCP systems to assure food safety. An additional aspect of this question is the issue of techniques for communicating these different skills to industry and to regulators.

2. How can an expert system that would assist the inspector in making regulatory decisions and help standardize inspectional activities be developed?

The focus of this researchable question is on assessing the writing of expert systems as aids to inspection officials in standardizing regulatory response to industry. The intent is to examine whether such systems can effectively array the range of information that inspectors need to consider when arriving at judgements concerning the disposition of product and the suspension

of processes that have failed to produce compliant product. The use of expert systems are not envisioned as "telling inspectors what to do". Rather, their use is intended to assure that inspectors have readily available the latest information about hazards, CCP's, regulatory requirements, etc, from which to make appropriate judgements about product disposition and processing controls. This appears to be a long-term initiative.

3. What information is needed by different target populations (consumers, regulatory agents, processors, producers, etc.)?

These questions focus on common issues that are reflected by each of the sub-committees-that is, what information is needed by particular individuals, how can that information be delivered to those individuals and how can we responsibly communicate about risk to targeted individuals? The individuals can be industry operators, distributors, food preparers, or consumers. For each of these individuals, it is important that they understand the food safety risks associated with their responsibilities in production, manufacture, distribution, preparation, and consumption. In the past, people understood the limits of science and technology in eliminating risks from raw and ready-to-eat meat and poultry. Even those food products exposed to a pathogen kill step can be temperature abused in distribution, causing risk of foodborne illness to re-emerge. USDA must clearly communicate about risks, limits of present knowledge, appropriate use of food safety interventions, behaviors, and practices. Prevention of foodborne illness is possible and achievable.

4. How do you get the information to the target populations in the most efficient manner?
Short term

(See question #3 response)

5. How do we efficiently and effectively communicate food safety risks to target populations?
Short Term

(See question #3 response)

APPENDIX D. Food Preparation and Consumption Subcommittee Research Areas and Researchable Questions.

The Food Preparation and Consumption area consists of retail food operations (sales, marketing, food service, institutional feeding establishments, catering, etc.) and consumer activities. This subcommittee acknowledged that pathogen reduction activities in retail operations are comparable to those found in in-plant processing activities. The objectives of the subcommittee were to identify research areas and researchable questions, prioritize research areas, and identify researchable questions as immediate (less than one year), short term (within two years), and long term (more than two years) goals.

Prevalence/Incidence/Epidemiology

1. What is the prevalence and incidence of human pathogens in meat and poultry and its relationship to foodborne illness?

Information is needed on the prevalence and incidence of the pathogen population in this segment of the food chain continuum. Information is also needed on emerging foodborne pathogen(s) and whether they are causative agents of foodborne illness. Relative to foodborne illness, identification of infected populations and measurement of the severity of the illness, would be valuable. Prevalence studies can be accomplished in the short-term. Incidence studies will be long-term.

2. What are the sources, points of entry, and opportunities for proliferation of bacteria within the retail and home portions of the food chain?

It is important to establish the sources of pathogens and periodically reassess them. Does the contamination come from the food worker or food preparer? At which points along the continuum does the pathogen enter the food chain, are there specific food handling practices that allow the pathogen to proliferate in the retail and home environment? Which pathogens persist in the retail and home environment? Sources of pathogens and their persistence in simulated retail/home environments can be accomplished in the short-term.

3. How can methods for detection and sampling frames for foodborne pathogens and the associated surveillance systems be improved?

Adaptation of current technologies to improve detection systems and sampling frames for foodborne pathogens is needed immediately. Of primary importance is the development of tests which are more rapid (e.g. elimination of an enrichment step). In the development of such tests,

consideration for accuracy, precision, safety, durability, ease-of-use and cost effectiveness must be taken into account. The possible adaptation of microbial detection systems for use in the retail/home environment could be a significant factor in surveillance. Additionally, these types of diagnostic systems could be used to assess thoroughness and effectiveness of equipment and product contact surface sanitation. It is important to recognize that the sampling frame (e.g., size, location of sample, frequency, etc.,) is linked to the detection system limitations. Adaptation of current technology is short-term while adaptation of more innovative technology for development of rapid tests is long-term.

The type of detection systems and sampling frames to be developed for the food processing segments of the continuum will be generally applicable to these retail operations. However, there would be no regulatory requirement for their use in retail operations. Research is also needed to determine if sample detection tools or techniques could be developed and made available for retail or home use by persons in high-risk groups for foodborne illness.

HACCP in Retail and Home Food Preparation

1. What is the scientific basis for identifying hazards, establishing critical control points and setting critical limits in the home/retail setting?

It is important to first identify the hazards by looking for the sources of pathogens and the influence of the process of food preparation on food borne pathogens. What are the refrigeration practices? What are the cooking protocols and food preparation practices? What are the post-cooking practices, holding temperatures, holding times; is there an opportunity for temperature abuse? What are the reheating practices? What practices give an opportunity for cross contamination to occur? After identification of the hazards, what are the location(s) of the critical control points along the food preparation chain? Then, what are the critical limits for each pathogen? Since the "retail" portion of the continuum is so varied, most hazard identification can be done immediately, however, complete hazard identification could be long term. Other components necessary for HACCP implementation can be accomplished in the short-term.

2. What methods for monitoring critical control points and verifying HACCP operations exist or can be developed? Can existing ones be improved?

Evaluation of current methods is needed to determine their usefulness and to determine if they can be adapted to a HACCP operation. Are the methods sufficient for their intended use, are they reliable, accurate and cost effective? What type of verification is needed for HACCP in retail food preparation? What optimal mechanisms are available to evaluate the effectiveness

of a HACCP system. Evaluation of current methods can be accomplished immediately while adaptation can be done in the short-term.

Technology/Technology Transfer

1. What interventions or control technologies exist or need to be developed to decrease risk of foodborne pathogens in a retail/home food preparation environment?

New products are being developed continuously. Concurrently, older technology is being applied or extended to other products while new marketing strategies are being employed to promote these as new, unique products. To insure the safety and effectiveness of these products, these technologies should be evaluated immediately. As scientific knowledge about new technologies and intervention for pathogen reduction becomes available, it must be evaluated. New, more effective or improved technologies may be developed long term.

Equipment and facility designs are being changed and improved on a continual basis. As these changes are tested and evaluated, the knowledge gained needs to be evaluated as to its impact on microbial food safety. The effects of improvements in packaging technology, such as time/temperature indicators, package design, shape, size, and composition should be evaluated in relation to food safety.

Another important feature to technology innovation is the criteria used to evaluate it. Is it safe? Reliable? Cost effective? Is it acceptable to the consumer? What is the consumer's perception or value for new technology? Will new or other hazards be introduced if this technology is used? These points need to be considered when technology is evaluated.

2. What retail practices can be altered to optimize food safety?

As scientific knowledge in relation to pathogen reduction and safe food handling practices becomes available, can these techniques be adapted and incorporated into retail activities? Not only should these practices or techniques promote food safety but they should be readily and easily adaptable to various retail situations. This is considered a long term initiative since practices are constantly changing and consequently need to be reassessed.

3. Which 'tools' could be adapted or developed for use in the food service industry or in the home?

Many tools and techniques are available for trained and laboratory personnel to determine if food products are pathogen safe. The short term question is can some of these techniques be adapted

as tools that can be used by people in the retail services or even by consumers in the home? In the long run, new technologies need to be developed for this use.

4. How can information technology be used/enhanced within USDA to better support research and other activities?

As a long term goal, can an integrated, on-line database that encompasses incidences and sources of foodborne diseases, outbreaks and information related to pathogen reduction be developed? Ultimately, government, industry, and academia cooperation and technology transfer must be encouraged to accomplish the desired goals. Some cooperation exists, however, improvement is needed for effective transfer of information. Enhancement of the flow of information about interventions to reduce pathogens in meat and poultry is a long term goal.

Economic Analysis and Risk Assessment

1. What is the size and characteristics of populations at increased risk for foodborne disease?

Specific segments of the population (e.g., neonates, individuals over 70, immunocompromised individuals, individuals with genetic predispositions to autoimmune diseases) are at increased risk to either the acute or chronic effects of foodborne pathogens. Effective risk assessments and economic analyses of pathogen reduction initiatives will be dependent on the availability of accurate estimates of the both extent and characteristics of these groups. An immediate need is an evaluation of currently available medical and demographic data to acquire an estimate of the scope of subpopulation with specific food safety needs. This should be augmented with a long term commitment to periodically assess the needs of at risk populations, particularly in relation to the likely emergence of new foodborne threats to public health.

2. What assessment techniques could be developed to evaluate the likely economic impacts (including impacts on consumer demand) associated with changes in technologies and changes in food safety behaviors and practices of food preparers?

Effective risk management strategies require an understanding of the economic and attitudinal factors that affect behavior of food preparers, both consumers and food service employees. A critical need is data on consumer behavior, such as consumer preferences for product attributes (e.g., safety, taste) and consumers' and food service employees' knowledge and perception of foodborne pathogens and associated illness. Consumer and industry surveys are the most appropriate approach currently available for gathering such information. It is essential that policy-relevant surveys be carried out as soon as possible to understand individuals' and firms' motivation and practices, although data collection is a long term and on-going process. Other

long run research and data collection are required to understand 1) how consumer confidence is enhanced by food safety regulations, 2) consumer preferences for avoiding foodborne illness, 3) consumer preferences toward risk control schemes (e.g., government inspection, consumer education, and self-protection), and 4) consumer willingness to buy lower risk foods and willingness to pay a premium for lower risk foods. Long-term research is also needed to refine current survey methodology, to improve conceptualization, and to develop alternative and/or complimentary data collection methodology.

3. What assessment techniques could be developed to evaluate the risks associated with changes in technologies and behaviors as practiced by food preparers and consumers? How can we determine if unintended hazards are created, including changes in occurrence and severity of hazards?

History provides a number of examples of how changes in the practices and technologies in food marketing, preparation and consumption can have unexpected effects on public health. Techniques are needed to systematically anticipate the effects that changes in retail food operations and consumer practices are likely to have on public health. A short term need is to assess and validate the potential effectiveness of available predictive microbiology models for predicting the behavior of pathogenic bacteria in retail and home food preparation operations. Long term needs include the integration of dose-response and predictive microbiology models to the techniques needed for conducting quantitative microbiological risk assessments. Similarly, techniques for systematically assessing the likely public health impact and risks associated with the introduction of new retail and home food preparation technologies (including new foods and food ingredients) and practices need to be developed. In addition to the development of methods for anticipating risks, an accompanying long term research need is the development of improved techniques for assessing the impact that microbial food safety intervention activities have had on effectively reducing the consumers' risks of foodborne disease.

4. What administrative and regulatory procedures or incentives need to be used to encourage the development and adoption of new technologies?

Research is needed to understand firms' attitudes toward initiating and adopting new technologies and the impact of regulations on costs of development and adoption. The development of new pathogen control technologies often requires long-term and significant financial commitment on the part of the developer, usually a commercial firm. Regulations can be devised to encourage the development and adoption of new technologies which optimally reduce foodborne health risks while producing reasonable rewards to firms. A long-term commitment to this research is required.

Consumer and Food Preparer Education/Risk Communication

1. How can we effectively and responsibly communicate food safety risks? How do consumers become aware of risks? How can people be motivated to change behavior? What type of education is needed? What kind of research is being conducted into consumer reaction to warning labels? How effective is our message delivery? Can we improve it? How? At which points along the chain from retail to consumer do we not have an adequate message delivery system? How can we evaluate/ improve delivery systems and effectiveness of food worker training? Can educational messages be used for control mechanisms?

This first set of research questions is preliminary and designed to allow the parties concerned to accurately determine the situation at hand, our current capabilities, and then to determine how best to proceed to motivate behavioral changes. To date, very little research has been conducted on risk communication as it pertains to food safety. Knowledge gained from this research and an analysis of our message delivery system is basic to building an effective system.

2. What types of monitoring systems and evaluation techniques can be developed to assess changes in knowledge levels and preferences of food preparers and consumers about food preparation and handling practices and interventions?

This second question is designed to complement and expand the first through developing monitoring and evaluation techniques. It a long term research goal to keep abreast of emerging changes in food preferences, handling, and consumption.

APPENDIX E. Developing a Framework for Priority Setting

In addition to identifying research areas and researchable questions, the subcommittees were also asked to consider criteria for establishing research priorities. A series of approaches and criteria were suggested by different working groups. This culminated in a joint meeting of the three subcommittees to discuss options and recommendations described below. The ranking and priority-setting discussions were conducted primarily by the USDA subcommittee participants.

The subcommittees felt that the effort to develop a framework upon which research priorities and related decisions could be based was a worthwhile endeavor. However, the subcommittees' time constraints restricted consideration to an initial assessment of potential approaches and criteria. The two examples provided below have not been rigorously evaluated or validated. Instead, they are presented as examples of approaches that should be considered by further study.

<u>It is the recommendation of the subcommittees that the Department convene a panel of food safety specialists to further consider and test the effectiveness of tools that can assist in the identification of research needs and the establishment of research priorities</u>. The composition of such a panel should be broad, consisting of research scientists, social scientists, scientists supporting regulatory activities, research administrators, and potential users of the research. Both scientific and social science research should be ranked and include such diverse research areas as veterinary, epidemiological and technological knowledge as well as demographic, psychological, behavioral, administrative and communication concepts.

When considering a specific foodborne agent within one of the broad research areas, the knowledge needed to identify, characterize and control the problem is often sequential and must be developed in an iterative manner. This makes the use of decision tools such as a decision tree feasible. As an example, a decision tree for the identification of priority research needs for a pathogenic microorganism for the slaughter/processing portion of the farm to table continuum is presented in Figure 1. The decision tree attempts to capture several different facets related to decision making at this stage. Prime attributes include the relative priority of research areas increase and decrease with time, research is an iterative process, and some areas of research must be accomplished before others can be effectively undertaken. The advantages of this approach are that it provides an overview of the status of the research needs within a microbiological problem, identifies critical needs, and provides a framework that identifies the complexity of the food safety issue while still is relatively easy to use. The disadvantage is that this approach is largely restricted to use to a single pathogen at a time and not designed to assess the relative priorities among various foodborne pathogens.

An approach utilized by the subcommittees was a matrix for aggregating and evaluating a body of expert opinion. The matrix (Table 1) considers each of the research areas against five criteria. Each research area is ranked (1 - 5) for each criterion. The criteria consider several broad areas that influence the relative importance of each of the research areas. The explanation of the criteria is provided in Table 2.

After the joint meeting of all subcommittee members, the criteria, shown in Table 2, were developed. The criteria were contrasted to other systems that have been developed for prioritizing research initiatives. One system derived from section 1402 of the National Agricultural Research, Extension and Teaching Policy Act of 1977 and amended in section 1602 of the FACT act could serve as a model for criteria. The criteria, which are similar to the ones developed by the subcommittees, are summarized here:

a. Will the research extend our basic knowledge?

b. Will the research significantly improve food safety?

c. Is the research innovative?

d. Will the results be broadly applicable?

e. Does the research address one or more of the purposes of agricultural research and extension?

The key to the use of this approach is that it is a means of objectively assessing the opinions of a body of experts who each bring different expertise and concerns to the decision process. The effectiveness of this approach is dependent on ensuring that the group of experts have achieved a general understanding of both the items to be ranked (e.g., the research areas) and the criteria used for the ranking. The experts should encompass the various stake-holders involved in the decision process. As an example, the subcommittee members used the matrix to evaluate the complete set of research areas that resulted from their deliberations. These results are summarized in Table 3. Under normal use of this methodology, the group of experts would be convened to examine the aggregate results of the ranking and to apply an intuitive evaluation of these results. The use of this methodology should be further tested under these parameters to determine its utility in ranking and prioritizing broad research areas.

The results of the exercise in overall ranking across all three subcommittees are presented in Table 3. There was little variation throughout the ranking of the research areas except for the top 5 or 6 areas. This is to be expected, since not all of the participants were familiar with topics within each of the researchable areas. Also, the similarity of questions in different

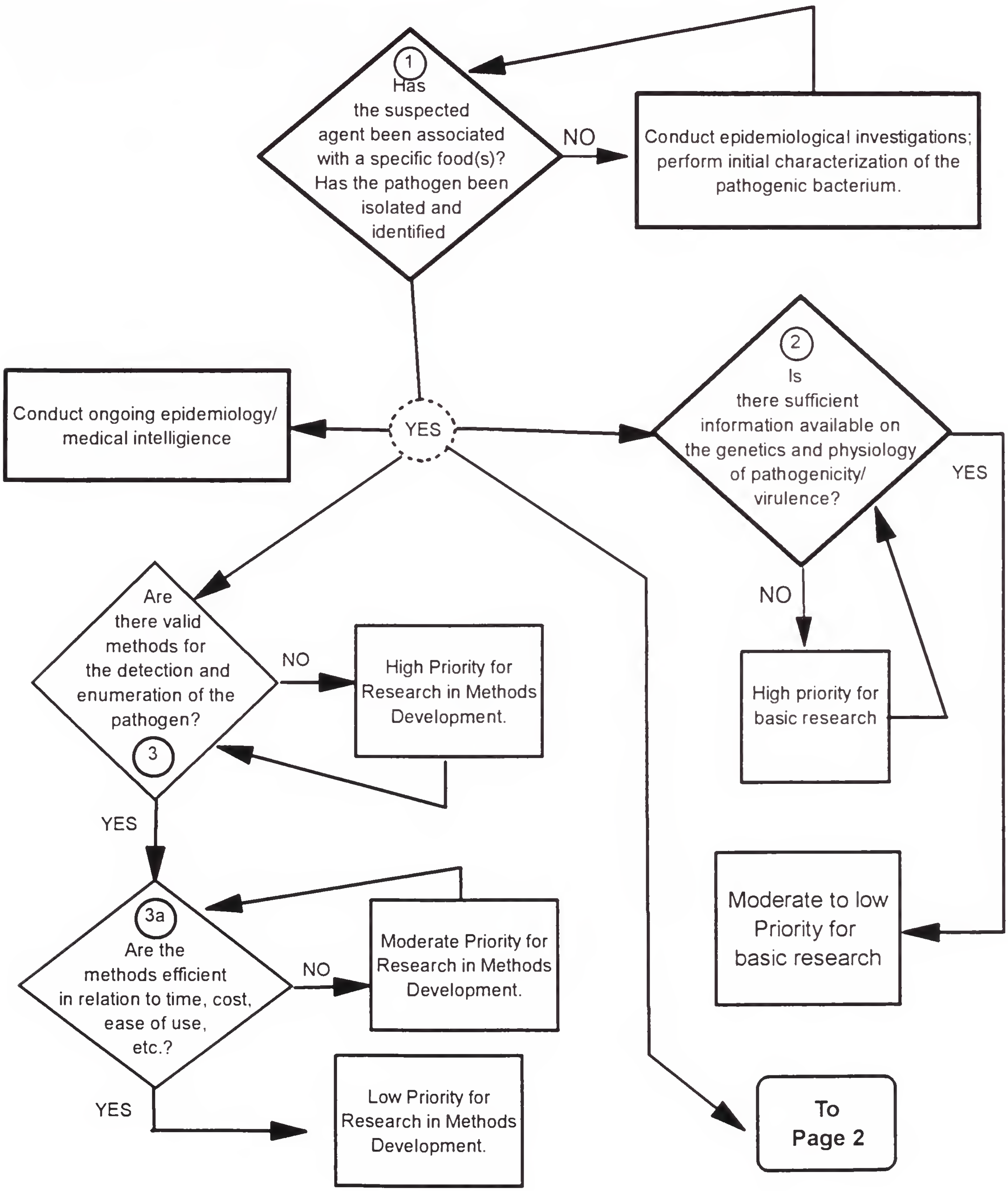
researchable areas may have contributed to the participants giving equal weight to those questions across the continuum. Other factors that may have contributed to the low discrimination among areas is the natural bias of expertise of each participant, the importance of one question within an area compared to the areas in general, and the tendency to rate short term or immediate goals as higher priority.

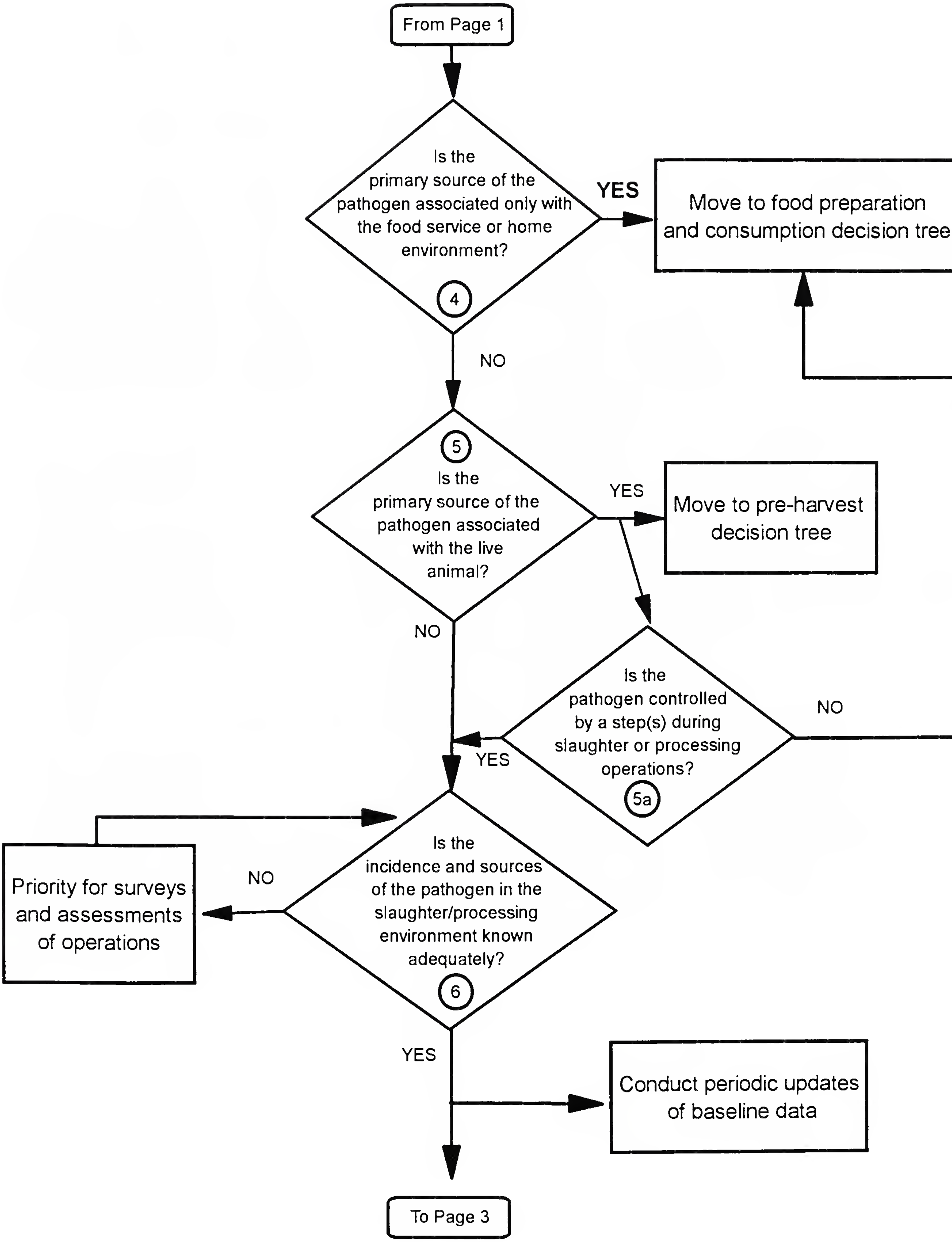
In addition to considering the use of ranking/decision tools, each subcommittee also attempted to arrive at consensus agreement on a ranking of the research areas within their particular segment of the farm-to-table continuum. The results of these discussions are displayed in Table 4.

In general, the rankings within each subcommittee reflect a knowledge-based approach that proceeds sequentially from acquiring new knowledge about microorganisms, to determining the means of applying that knowledge in intervention and control mechanisms, to assessing the implications of introducing those interventions, to communicating with and educating others about how those interventions have enhanced food safety. The sequential approach moderates within different segments of the continuum. For example, risk communication and education rises in ranking as one moves through the continuum from live animal to food preparation and consumption.

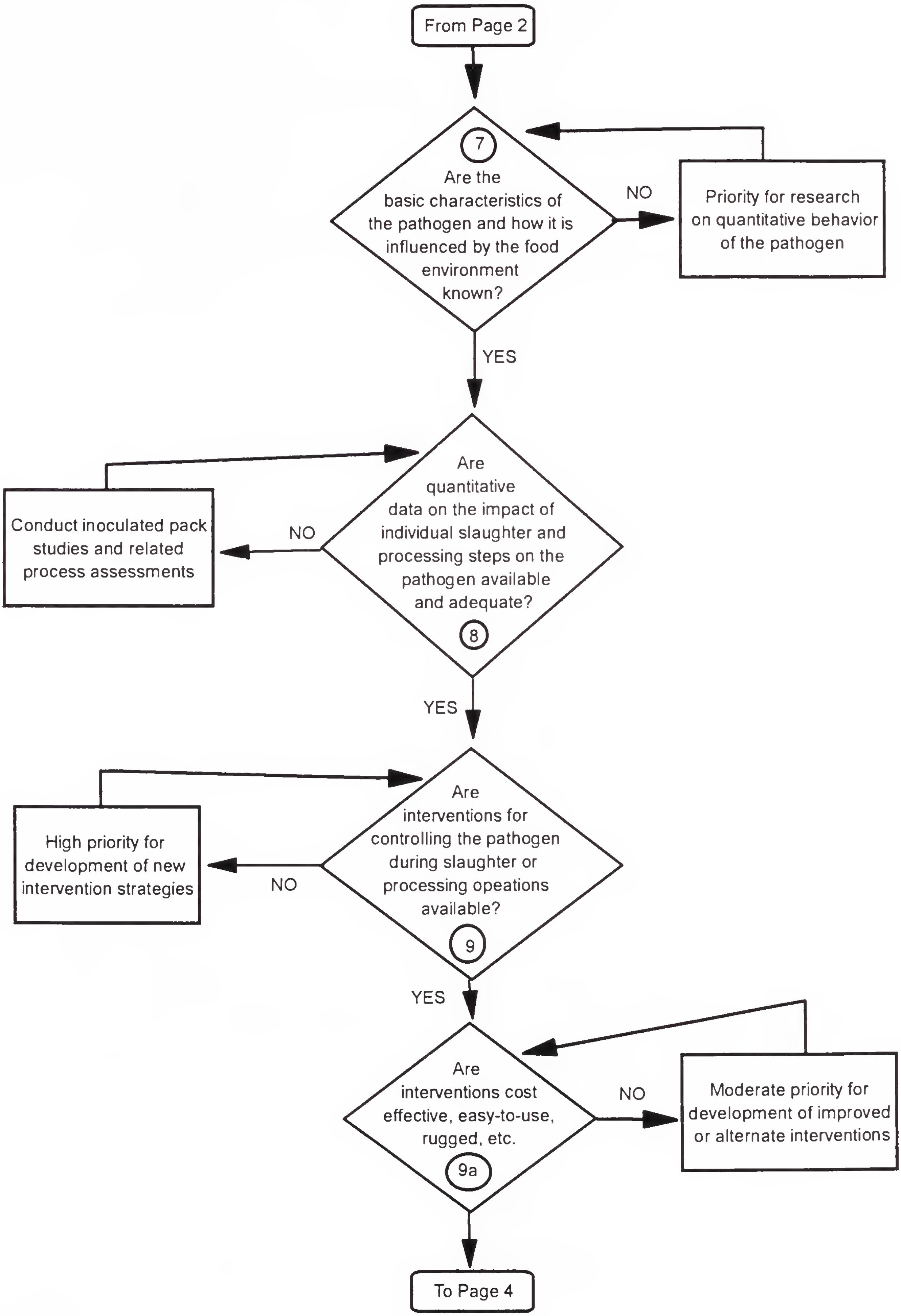
In Table 4, it is noted that the Slaughter and Processing subcommittee was unable to reach consensus on the ranking of the research areas. The differences in opinion centered on the placement of risk communication and education within the overall ranking. Some members of that subcommittee believed strongly that a departure from the sequential, knowledge-based approach was appropriate within the slaughter and processing arena to assure that the Department's proposed mandate to introduce HACCP systems in Federally-inspected meat and poultry establishments would be adequately supported with the communication and education tools needed by industry members, regulators, and the public. These members felt that, at this time, HACCP and risk communication and education needed to rank 1 and 2 within this segment of the continuum.

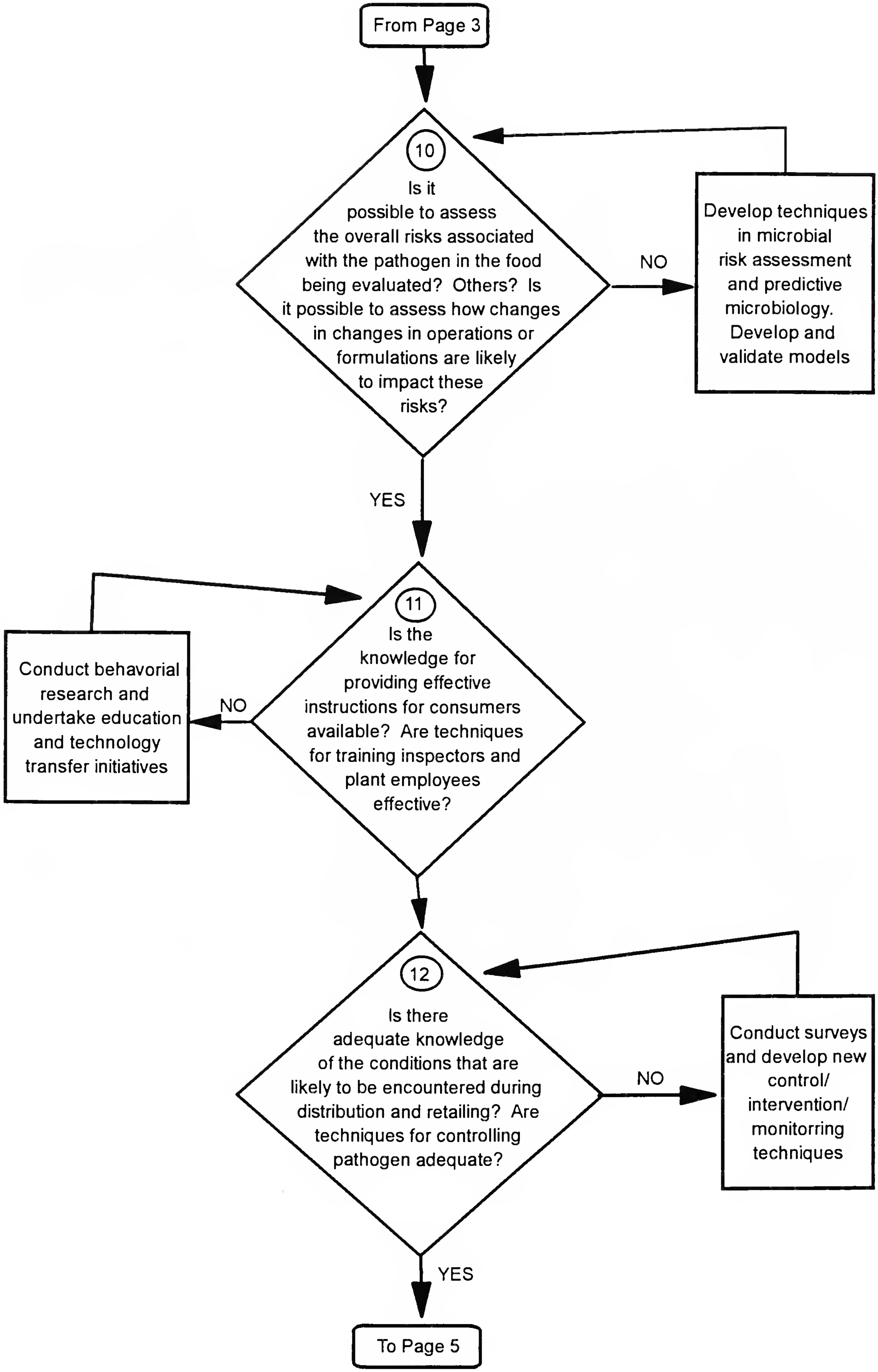
Figure 1.
Decision Tree for Prioritizing Research on Microbial Food Safety Concerns Associated with Slaughter/Processing/Distribution Operations





From Page 1
Is the primary source of the pathogen associated only with the food service or home environment?
4
YES
Move to food preparation and consumption decision tree
NO
5
Is the primary source of the pathogen associated with the live animal?
YES
Move to pre-harvest decision tree
NO
Is the pathogen controlled by a step(s) during slaughter or processing operations?
5a
NO
YES
Priority for surveys and assessments of operations
NO
Is the incidence and sources of the pathogen in the slaughter/processing environment known adequately?
6
YES
Conduct periodic updates of baseline data
To Page 3


From Page 2
7
Are the basic characteristics of the pathogen and how it is influenced by the food environment known?
NO
Priority for research on quantitative behavior of the pathogen
YES
Are quantitative data on the impact of individual slaughter and processing steps on the pathogen available and adequate?
8
NO
Conduct inoculated pack studies and related process assessments
YES
Are interventions for controlling the pathogen during slaughter or processing opeations available?
9
NO
High priority for development of new intervention strategies
YES
Are interventions cost effective, easy-to-use, rugged, etc.
9a
NO
Moderate priority for development of improved or alternate interventions
To Page 4



From Page 3
10
Is it possible to assess the overall risks associated with the pathogen in the food being evaluated? Others? Is it possible to assess how changes in changes in operations or formulations are likely to impact these risks?
NO
Develop techniques in microbial risk assessment and predictive microbiology. Develop and validate models
YES
11
Is the knowledge for providing effective instructions for consumers available? Are techniques for training inspectors and plant employees effective?
NO
Conduct behavorial research and undertake education and technology transfer initiatives
12
Is there adequate knowledge of the conditions that are likely to be encountered during distribution and retailing? Are techniques for controlling pathogen adequate?
NO
Conduct surveys and develop new control/ intervention/ monitorring techniques
YES
To Page 5

From Page 4

Conduct ongoing medical intelligence. Conduct baseline data updates and market basket surveys.

Provide sufficient resources to stimulate improvement of known approaches and encourage innovations through the slaughter - processing - distribution - retail system.

Table 1. Summary of research areas and questions by subcommittees.

CRITERIA FOR SETTING/EVALUATING RESEARCH PRIORITIES FOR USDA	LIVE ANIMAL SUBCOMMITTEE						SLAUGHTER/PROCESSING SUBCOMMITTEE						FOOD PREPARATION & CONSUMPTION SUBCOMMITTEE					PUBLIC HEALTH SURVEILLANCE & MONITORING
	A[a]	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1. Provides knowledge needed for food safety problem resolution																		
2. Increase innovation for improving economic competitiveness and enhances the ability to deal with new threats to public health.																		
3. Can be achieved with current technology.																		
4. Meets public policy goals of the Department																		
5. Cost/benefit analysis favors implementation																		
TOTAL																		

a. Assign 1 - 5 points for each criterion.

Table 2. Pathogen Reduction Task Force Subcommittee Criteria for Ranking Research Areas

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The underlying principle or goal of food safety research is to aid in the production of a safe, wholesome, nutritious product that is readily affordable.

1. Provides <u>knowledge</u> needed for food safety problem resolution.
    - Does it solve an immediate problem?

2. Increases <u>innovation</u> for improving economic competitiveness and enhances the ability to deal with new threats to public health.
    - Does it address public health concerns?
    - Does it decrease cost of producing a safer product?
    - Does it decrease inspection/regulation costs?
    - Does it enhance innovation in production, processing and preparation?
    - Does it aid in the rapid identification and control of emerging microbial food safety threats to public health?

3. Can be achieved with current <u>technology</u>.
    - Does the current technology need to be adapted for use?

4. Meets <u>public policy</u> goals of the Department.
    - Does it enhance our goal of global competitiveness?
    - Does it enhance the department's scientific infrastructure?
    - Does it promote voluntary compliance or proactive policies?
    - Does it promote interagency coordination and cooperation?
    - Does it meet the department's need to provide consumers and others (interest groups) appropriate information?

5. <u>Cost/benefit</u> analysis favors implementation.
    - Is it economically feasible?

Note: The points listed below each criteria are meant to expand the concept, however they are not exclusive.

Table 3. Relative Ranking of Research Areas Across All Subcommittees. Maximum average is 25 points.

Rank	Research Areas (Subcommittee[1])		Point Total	Average
1	C.	Live Animal ("Pre-harvest") HACCP (LA)	360	20.0
2	M.	Prevalence/Incidence/Epidemiology (FP&C)	358	19.9
3	I.	Slaughter/Processing HACCP (S/P)	354	19.7
4	G.	Prevalence/Incidence/Sources (S/P)	349	19.4
5	L.	Risk Communication and Education (S/P)	343	19.1
6	H.	Microbial Physiology/Ecology (S/P)	342	19.0
7	A.	Ecology and Epidemiology (LA)	337	18.7
8	J.	Technology Development and Transfer (S/P)	336	18.7
8	B.	Pathogenicity/Virulence/Microbial Physiology/Genetics (LA)	336	18.7
10	Q.	Technology/Technology Transfer (FP&C)	334	18.6
11	E.	Risk Communication/Technology Transfer (LA)	328	18.2
11	O.	Consumer and Food Preparer Education/Risk Communication (FP&C)	328	18.2
13	N.	HACCP in Retail and Home Food Preparation (FP&C)	324	18.0
13	R.	Public Health Surveillance and Monitoring	324	18.0
15	K.	Economic Analysis and Risk Assessment (S/P)	321	17.8
16	D.	Economic Analysis/Risk Assessment (LA)	316	17.6
17	P.	Economic Analysis and Risk Assessment (FP&C)	314	17.4
18	F.	Traceback (LA)	286	15.9

[1] Subcommittee designation: **LA** = Live Animal; **S/P** = Slaughter/Processing; **FP&C** = Food Preparation and Consumption.

Table 4. Tentative Rank of Priority Research Areas Within Each Subcommittee

Live Animal Subcommittee

1. Ecology and Epidemiology
2. Pathogenicity/Virulence/Microbial Physiology/Genetics
3. Live Animal ("Pre-harvest") HACCP
4. Economic Analysis/Risk Assessment
5. Risk Communication/Technology Transfer
6. Traceback

Slaughter/Processing Subcommittee

1. Prevalence/Incidence/Sources
2. Microbial Physiology/Ecology
3. Slaughter/Processing HACCP
4. Risk Communication and Education
5. Economic Analysis and Risk Assessment
6. Technology Development and Transfer

(Tentative rankings though no consensus was reached.)

Food Preparation and Consumption Subcommittee

1. Prevalence/Incidence/Epidemiology
2. HACCP in Retail and Home Food Preparation
3. Consumer and Food Preparer Education/Risk Communication
4. Economic Analysis and Risk Assessment
5. Technology/Technology Transfer

Overall Research Area

1. Public Health and Production Animal Surveillance and Monitoring

APPENDIX F. Pathogen Reduction Task Force Subcommittee Members

Live Animal Subcommittee

Bonnie Buntain	APHIS
Dan Lazenby	FSIS
Jeanne Axtell	FSIS
Peter Brayton	CSRS
Robert Buchanan	ARS
John DeLoach	ARS
Elizabeth Hughes	P&SA
John Acree	APHIS
Kenneth Hall	ES
Jan Singleton	ES
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Angel Ramos	APHIS
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Slaughter and Processing Subcommittee

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